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Tobacco harm reduction: The need for new products that can compete with cigarettes ☆

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HIGHLIGHTS

- Tobacco harm reduction aims to reduce illness and death caused by smoking tobacco.
- The medical and regulatory consensus is that nicotine itself is relatively safe.
- Snus use in Sweden provides strong evidence in support of harm reduction.
- E-cigarettes are seen by many smokers as an attractive alternative to cigarettes.
- Regulated, safer nicotine alternatives may substantially improve public health.

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ABSTRACT

Over the last 50 years, the concept of tobacco harm reduction has been well established. It is now understood that nicotine itself is not very harmful and nicotine replacement therapy products have been widely used as an aid to quit, reduce to quit or temporarily abstain from smoking for many years. The popularity of the unlicensed electronic cigarette has increased despite an unknown risk profile and snus use in Sweden provides strong evidence in support of a harm reduction strategy. The regulatory environment around harm reduction has changed in the UK and is continuing to evolve across the globe. The need for more appealing, licensed nicotine products capable of competing with cigarettes sensorially, pharmacologically and behaviourally is considered by many to be the way forward. The significant positive impact on public health that could be gained from encouraging people to switch from cigarettes to licensed medicinal nicotine products cannot be ignored.

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1. Harm reduction: history and current perspectives

The concept of tobacco harm reduction is well established. In 1976, Professor Michael Russell wrote: "People smoke for nicotine but they die from the tar", and suggested that the ratio of tar to nicotine could be the key to safer smoking, specifically a low-tar, medium-nicotine cigarette (Russell, 1976). Despite innovations in the mid-1970s, several filtered products delivered as much tar and nicotine as the original, unfiltered brands (Kozlowski & O'Connor, 2002). As understanding improved, new research in 1982 confirmed that smokers inhaled less smoke from a nicotine-enriched cigarette than a control cigarette, equal in all aspects besides nicotine yield (Fagerström, 1982).

Since the White Paper, 'Smoking Kills', was published in 1998 (Department of Health, 1998), a variety of tobacco-control policies to reduce smoke prevalence have been implemented in the UK, and around the world (Royal College of Physicians, 2007). The National Institute for Health and Care Excellence (NICE) defined tobacco harm reduction as "reducing the illnesses and deaths caused by smoking tobacco — among people who smoke and those around them" (NICE, 2011). In parallel, medical opinion has evolved, recognizing the potential health benefit of smokers shifting from cigarettes to pharmaceutically-regulated nicotine products. In fact, in the last decade, the medical community has urged regulators to consider harm reduction strategies to reduce rates of smoking (NICE, 2011; Royal College of Physicians, 2007, 2012). Similarly, in the USA, the Family Smoking Prevention and Tobacco Control Act of 2009 aims to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users (FDA, 2009).

Although medicinal nicotine products were initially regulated as prescription only, they have been available over the counter (OTC) as a General Sales List product for a decade in many countries. Further restrictions on the use of nicotine replacement therapy (NRT) in specific populations, such as pregnant women, those with heart disease, diabetes, liver or kidney problems, and children aged 12–18 years, have gradually been minimized (MHRA, 2005), and the indication for NRT extended to include 'cut down to quit' and 'temporary abstinence', along with cessation (MHRA, 2010a). Most regulators, therefore, apply no time limit for NRT use to support reduction, confident that this alone facilitates quitting and may have direct health benefits, not least to those living with the smoker. Similarly, many countries also support 'temporary abstinence' (Gartner, Hall, & McNeill, 2010). An overview of approaches over time in the UK is presented in Fig. 1.

In 2009, the UK Medicines and Healthcare products Regulatory Agency (MHRA) approved an extension to include harm reduction as an indication for the Nicorette® Inhalator (McNeil AB, Helsingborg, Sweden) (MHRA, 2009). Resulting from the review of its approach to smoking cessation in 2010, it advocated an indication for harm reduction for all licensed nicotine-containing products (MHRA, 2010b).

The recently updated public health strategy in the UK recognizes that many smokers may not want, or be able, to quit smoking, but would like a safer alternative to cigarettes (HM Government, 2011). NICE guidelines in the UK published in June 2013 recommend medicinal nicotine use on a long-term basis when needed to help people stop, cut down prior to quitting, reduce their level of, or temporarily abstain from, smoking. These guidelines cover the use of licensed nicotine-containing products, and those that might be licensed by the MHRA in the future such as those electronic cigarettes (e-cigarettes) demonstrating the necessary quality and safety standards (NICE, 2013).

In other countries, a harm reduction strategy is supported by an increasing number of experts. While NRT is only licensed in this way in the UK, the long-standing Swedish policy of accepting moist snuff (snus) to compete with burnt tobacco has provided evidence of significant health benefits; male smoking and tobacco-related mortality in Sweden are among the lowest in the world (Rodu, Stegmayr, Nasic, & Asplund, 2002). There is also evidence suggesting that snus uptake can result in moving from high- to low-risk tobacco use or quitting altogether (Ramström, 2011). This indicates the benefits that might conservatively be expected if NRT was more widely licensed for harm reduction.

2. Safety of nicotine as an alternative to smoked tobacco

It is generally understood that it is not nicotine itself that is harmful, but the method of delivery, i.e. burning tobacco (ASH, 2007). Moreover, it has been proposed that a switch of only 1% of smokers a year from smoking to less harmful nicotine sources could potentially save around 60 000 lives in 10 years in the UK alone (Lewis, Arnott, Godfrey, & Britton, 2005).

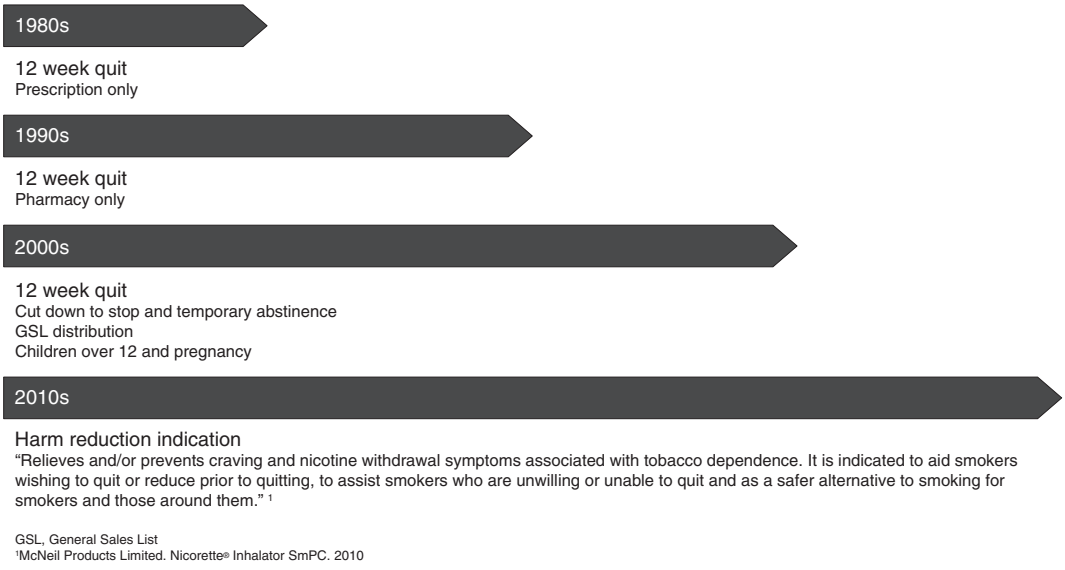

Fig. 1. Nicotine replacement therapy regulation in the UK over the last 30 years.