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Editorial

European Respiratory Society statement on novel nicotine and tobacco products, their role in tobacco control and "harm reduction"

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European Respiratory Society statement on novel nicotine and tobacco products, their role in tobacco control and "harm reduction"

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Novel nicotine and tobacco products and harm reduction

- What are novel and emerging nicotine and tobacco products?

A growing number of new tobacco and nicotine products have emerged in recent years and are especially popular among adolescents and young adults. These are collectively known as "Novel and Emerging Nicotine and Tobacco Products"[1,2] and include electronic cigarettes, heated tobacco products, and nicotine pouches.

Electronic-cigarettes (e-cigarettes or vapes) including electronic nicotine delivery systems (ENDS) or electronic non-nicotine delivery systems (ENNDS), utilise a battery to heat an e-liquid solution containing flavourings, additives, and, with the exception of ENNDS, nicotine[3]. Notably, disposable e-cigarettes have recently gained significant popularity, especially among adolescents and young adults[4]. The majority of e-cigarettes available in the market contain a high concentration of nicotine which has addictive potency[5]. Consequently, their usage among young people has reached epidemic levels in many countries[3,4].

Heated tobacco products (HTPs), also known as "heat-not-burn" products, utilise electrical devices to heat tobacco sticks, producing nicotine-containing aerosols without combustion[6]. Unlike e-cigarettes, these products do contain tobacco and exhibit diversity in heating device styles and tobacco types. However, similar to e-cigarettes, HTPs incorporate novel features and designs to attract users, resembling the experience of smoking traditional cigarettes.

Another emerging product is nicotine pouches, originating in Scandinavia but gaining popularity with users in the European region and beyond[7]. These pouches resemble tobacco pouches (snus) used in Sweden and are placed under the upper lip to release nicotine. Unlike snus, which is known to have adverse health impacts, including the development of specific cancers[8], nicotine pouches do not contain tobacco, but nicotine powder, salts, flavourings, and sweeteners, making them particularly appealing to younger individuals[9,10]. It is unknown whether these differences will translate into different risk profiles. Furthermore, nicotine pouches offer discreet usage, attracting non-smokers and youth[9]. Some users turn to nicotine pouches as a way to circumvent smoke-free regulations[10]. Currently, nicotine pouches are not subject to EU tobacco product regulations, allowing marketing without packaging regulations or health warnings[7,10]. Advertisements target younger populations, raising concerns about the popularity of nicotine pouches among the youth[11].

- What is the tobacco industry's so-called "harm reduction" strategy?

The concept of harm reduction originated in drug use[12], recognising that complete abstinence may not always be achievable. Instead, it proposes helping individuals transition to less harmful alternatives[13]. However, the tobacco industry exploited this concept and adopted a strategy of marketing novel nicotine and tobacco products as less harmful than traditional cigarettes[7]. Yet, these products allow the tobacco industry to maintain its profits in a context of declining smoking prevalence[1,14]. Ongoing scientific and legislative debates centre around concerns regarding the long-term health impacts and safety of these products[7,14]. Currently, there is insufficient scientific evidence to conclusively establish the reduced risk claimed by the tobacco industry for any of these novel products when compared to conventional cigarettes.

- What are the health effects of novel nicotine and tobacco products?

Despite their diverse forms, many novel products contain high levels of nicotine and toxic substances, posing risks and contributing to initiation and dependence of use among young individuals[15]. Exposure to nicotine, which is highly addictive and detrimental to brain development until age 25[16], may lead to addiction and dependency-related outcomes in the younger population[17]. While e-cigarettes are devices built predominantly to deliver nicotine, they emit harmful vapour consisting of hundreds of chemicals, including toxins with uncertain effects[17,18], irrespective of their nicotine content. An Australian toxicological review identified 243 unique chemicals, including known poisons, and banned substances in non-nicotine e-cigarette liquids. Among these, carbonyls like formaldehyde, acetaldehyde, and acrolein, which are linked to adverse health outcomes[19]. Furthermore, studies have voiced concerns that e-cigarette use may be associated with increased susceptibility to COPD, lung/cardiovascular diseases, and increased exposure to harmful chemicals and carcinogens use[20,21]. A recent extensive review of studies provides strong evidence demonstrating that vaping e-cigarettes could cause acute (short-term) lung injury, poisoning, burns, seizures, and adverse respiratory symptoms particularly in youths[17,22]. Recently in the US, an influx of young patients hospitalised due to e-cigarette or vaping-associated lung injury (EVALI)[23] from using e-cigarettes highlighted the potential public health risks.

HTPs heat tobacco instead of burning it, which is claimed by the tobacco industry to reduce levels of harmful substances typically formed during tobacco combustion[24]. However, similar to vaping e-cigarettes, users of HTPs can still be exposed to other potentially harmful

substances[1,25]. Lower exposure levels to harmful substances in these products do not necessarily translate to lower risk of cardiovascular diseases[26]. This is due to the non-linear relationship between exposure and effects, where the duration and level of exposure play significant roles[27]. For instance, despite reduced emissions compared to traditional cigarettes, HTPs have been associated with elevated heart rate, increased blood pressure, arterial stiffness, vascular endothelial dysfunction, and lung dysfunction[28,29], which may suggest deteriorating cardiovascular and lung health[30]. Furthermore, as HTPs are relatively new to the market, their long-term health effects and risks of HTPs remain unclear[31]. Although marketed as safer alternatives to traditional smoking, HTPs are not risk-free and pose an emerging public health concern.

Nicotine pouches are also marketed by the tobacco industry as harm reduction alternatives for cigarette and oral tobacco products users[9,15]. These pouches contain nicotine salts, resulting in higher nicotine levels compared to most smokeless tobacco products[32]. However, the safety of these new products remains unclear due to limited published research. Concerns arise from emerging evidence that highlights alarmingly high nicotine contents in certain pouches, particularly regarding their potential impact on oral health[33,34]. Additionally, carcinogenic substances in nicotine pouches have been shown to have genotoxic effects, which may contribute to tumour growth[33].

In summary, e-cigarettes, HTPs, and nicotine pouches are relatively new to the market compared to conventional cigarettes. However, with the exception of ENNDS, they are addictive due to their nicotine content and, although the long-term health effects of these products are not fully understood, emerging literature suggests potential health risks for all of them.

Evidence based positions on novel products and their role on tobacco "harm reduction".

Based on the latest evidence, the ERS positions on novel products and their role in tobacco "harm reduction" are discussed in the light of *reduction of harm, effects on public health*, and *smoking cessation*. Table 1 presents a point-by-point comparison between the current statement and the previous 2019 statement[35] on tobacco harm reduction.

- Reduction of harm

Position 1: *Despite the tobacco industry's claims of so called "harm-reduction", there is legitimate concern regarding the potential long-term health risks of novel products.*

The ERS maintains its stance that the claim that novel products are less harmful lacks robust independent scientific support and is instead simply exploited and misused by the tobacco industry for commercial gain[1,14]. As noted above, these products are relatively new compared to conventional cigarettes, and our understanding of their long-term health effects remains limited. However, since the 2019 ERS statement[35], accumulating evidence indicates potential adverse effects on respiratory and cardiovascular function, contributing to the development of chronic respiratory and cardiovascular diseases in humans[17,20,36]. Given there is no safe level of exposure to these substances, the ERS position remains that all nicotine or tobacco products inherently carry risks, particularly considering their uncertain long-term health impact.

Position 2: *Much of the evidence about harm reduction comes from the cigarette industry itself, which has a track record of manipulating science to further its financial interests.*

Driven by commercial objectives, the tobacco industry has a vested interest in claiming novel products have reduced risks. The tobacco industry has a well-documented history of deception, exemplified by a series of deliberate actions since the 1950s: denial of the smoking-lung cancer link[37], followed by claims of reduced harm from filter cigarettes[38], then promoting "healthier" alternatives such as light and mild cigarettes despite contradicting evidence[39]. This pattern highlights the industry's consistent prioritisation of profits over public health concerns.

Emerging evidence underscores the necessity to scrutinise the industry's novel product science, notably their attempts to influence the scientific debates in favour of novel products and "harm reduction". Recent reviews of these products revealed that many pro-harm reduction studies were industry-funded and exhibit substantial risk of bias[36,40]. Independent research is crucial for obtaining reliable information on the safety and risks of these products, enabling a more unbiased understanding of their "harm reduction" potential and impact on public health[17,36].

- Effects on public health

Position 3: *Even assuming that novel nicotine and tobacco products may present lower risks for individual users than smoked tobacco, they can cause net harm at a population level.*

While evidence suggests that some novel products could potentially lower individual risks for heavy smokers who have been unsuccessful in quitting using other evidence-based methods[36,41,42], it is crucial to consider the potential harm they may pose at the population level, especially among nicotine- or tobacco-naive individuals and the younger population.

Without strong regulation, the availability and promotion of novel and emerging products may lead to initiation of tobacco use among non-smokers. Similarly, it could prevent smokers from quitting completely, or lead to dual or poly-product use, significantly contributing to the global burden of tobacco[43,44].

The ERS emphasizes the importance of carefully assessing the use of novel tobacco products in tobacco control, considering potential risks and their long-term "net" impact on population health. As a result, the ERS maintains a cautious stance and does not recommend the use of novel products.

Position 4: *Increasing evidence shows that novel tobacco and nicotine products constitute gateways towards nicotine addiction and the initiation of smoking among youth.*

The emergence of novel nicotine and tobacco products raises concerns about addiction and health risks among young people[15]. Evidence suggests that non-smoking youths who use e-cigarettes could increase their chance of using cigarettes in later life[45,46]. Furthermore, the appealing flavours and advertisements associated with these products play a significant role in steering adolescents towards nicotine addiction. A recent review of 189 studies on vaping e-cigarettes also concluded that non-smoking youths who use e-cigarettes have substantially higher likelihood of starting smoking[17]. Although gathering evidence on the causal nature of this association is challenging, the ERS recognizes the harmful health effects and gateway potential of e-cigarettes towards cigarette smoking, particularly among young people[18].

Position 5: *Failure to consider contextual factors may result in population-wide harm from novel nicotine and tobacco products.*

Harm reduction at the population level should consider contextual variations in tobacco control across countries, taking into account factors such as product accessibility, legislation and policies, user profiles, and the stages of the tobacco epidemic[47].

Under specific controlled circumstances, such as in countries with low smoking prevalence and in clinical settings, some of these products may offer potential risk reduction for heavy smokers who would not otherwise quit smoking[48]. However, the regulatory landscape for these products, as well as the broader context vary from country to country. This heterogeneity introduces potential adverse effects at the population level. Novel products, if not regulated effectively, could renormalise tobacco and nicotine use, impede smoking cessation initiatives and attract new generations of nicotine consumers, leading to addiction and the normalisation of smoking.

In light of these complexities, adherence to the "precautionary principle" is crucial for the tobacco control community. This principle emphasises proactive measures in the face of potential harm to human health or the environment, even when causative relationships lack full scientific consensus[49]. By embracing this principle, the tobacco control community ensures vigilant regulation of these products, prioritising public health while minimising potential harm.

- Smoking cessation

Position 6: *Quitting smoking entirely is the best option.*

Recent research has examined the use of e-cigarettes to aid heavy smokers in quitting in clinical settings[41,42]. While some instances show their effectiveness, particularly in high-income countries like the UK[48], uncertainties persist regarding their effectiveness outside clinical settings, the overall balance of risks and benefits, and the long-term health impact of novel products for those who continue using them after they have quit smoking.

The ERS maintains a firm position that all nicotine and tobacco products are highly addictive and harmful. For current smokers, complete cessation of all nicotine products is the recommended goal to achieve freedom from addiction and reduce tobacco-related diseases[1,35]. Furthermore, promoting complete cessation is the optimal public health strategy for increasing quit rates and reducing smoking consumption. Consequently, the ERS does not support the use of these devices as replacement therapy for current smokers; when cessation aids are required, it is preferable to use evidence-based interventions, such as Nicotine Replacement Therapy (NRT) or tobacco cessation medications[50].

Position 7: *Evidence suggests novel tobacco and nicotine product users often engage in dual or poly tobacco product use, instead of fully replacing conventional cigarettes for harm reduction or cessation.*

The tobacco industry's claim of "harm reduction" is based on the unfounded assumption that smokers will replace conventional cigarettes completely with novel products. However, many continue to smoke or use cigarettes concurrently as dual or poly users[44,51], risking higher exposure to toxicants and nicotine dependence[52]. This trend is evident from population-based studies, which highlighted a large proportion of novel product users were also concurrent cigarette smokers (dual or poly- users)[51,53,54].

Position 8: *There is no evidence of hardening (high dependence and low motivation to quit) among the smoking population over time, and the tobacco industry's claim that existing tobacco control measures are ineffective is misleading.*

The tobacco industry has misleadingly exploited the concept of "harm reduction", suggesting that complete nicotine and tobacco cessation is not always possible or desired by the users[35]. However, recent evidence has shown that there is no hardening of smoking populations, and instead indicates a shift towards lighter smoking patterns over time[55-57]. The 2020 Eurobarometer data reveals that over 51% of current smokers in the European Union have attempted to quit, with the majority of users doing so without aids[51]. Furthermore, smoking prevalence in EU member states has declined over the last decade, leading to a reduction in daily smokers[58]. These findings challenge the industry's claims and highlight the effectiveness of tobacco control policies in reducing tobacco use and promoting smoking cessation worldwide.

Conclusions

The ERS Tobacco Control Committee draws the conclusion that we still lack sufficient independent evidence to support the tobacco industry's so-called "harm reduction" claim. All these nicotine products remain highly addictive and harmful. We must not allow the industry to exploit these products and undermine the existing implementation of the Framework Convention on Tobacco Control at any level. Reducing tobacco use and protecting youth from addiction to emerging products that may normalise tobacco use should be a top priority.

The EU prioritises tobacco control for disease prevention and aims for a "tobacco-free generation" by 2040. Consequently, the ERS does not recommend any lung-damaging products and cannot recommend harm reduction as a population-based strategy to reduce smoking and aid quitting.

Members of the ERS Tobacco Control Committee:

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Table 1. Update of the current 2023 statement relative to the 2019 statement on tobacco harm reduction.

Theme	**2019 statement**[35]	**2023 statement**
Reduction of harm	Argument 4: The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are generally less harmful.	Position 1: Despite the tobacco industry's claims of so called "harm-reduction", there is legitimate concern regarding the potential long-term health risks of novel products.
	Argument 7: The tobacco harm reduction strategy is based on incorrect claims that we cannot curb the tobacco epidemic.	Position 2: Much of the evidence about harm reduction comes from the cigarette industry itself, which has a track record of manipulating science to further its financial interests.
Effects on public health	Argument 5: Alternative nicotine delivery products can have a negative impact on public health even if "stick-by-stick" they turn out to be less harmful than conventional cigarettes.	Position 3: Even assuming that novel nicotine and tobacco products may present lower risks for individual users than smoked tobacco, they can cause net harm at a population level.
		Position 4: Increasing evidence shows that novel tobacco and nicotine products constitute gateways towards nicotine addiction and the initiation of smoking among youth.
		Position 5: Failure to consider contextual factors may result in population-wide harm from novel nicotine and tobacco products.
Smoking cessation	Argument 1: The tobacco harm reduction strategy is based on incorrect claims that smokers cannot or will not quit smoking.	Position 6: Quitting smoking entirely is the best option.
	Argument 6: Smokers see alternative nicotine delivery products as a viable alternative to the use of evidence-based smoking cessation services and smoking cessation pharmacotherapy.	Position 7: Evidence suggests novel tobacco and nicotine product users often engage in dual or poly tobacco product use, instead of fully replacing conventional cigarettes for harm reduction or cessation.
	Argument 2: The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery	Position 8: There is no evidence of hardening (high dependence and low motivation to quit) among the smoking population over time, and

	products are highly effective as a smoking cessation aid.	the tobacco industry's claim that existing tobacco control measures are ineffective is misleading.
	Argument 3: The tobacco harm reduction strategy is based on incorrect assumptions that smokers will replace conventional cigarettes with alternative nicotine delivery products.	

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