

Framework Convention on Tobacco Control, challenges and prospects for WHO

FROM TOBACCO CONTROL TO RISK REDUCTION,
THE OPINION OF EXPERTS BETWEEN BANS AND INNOVATION



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The damages of smoking

Every year, more than 36 million deaths worldwide are recorded as deaths from Non-Communicable Diseases (NCDs). These are mainly cardiovascular and respiratory diseases, cancer and diabetes. 63% of deaths globally are related to NCDs, and over 90% of NCD-related deaths occur in low and middle-income countries. The World Health Organization (WHO), in its report “Invisible Numbers”, published in 2022¹, analyses the problem, stating that it is one of the greatest challenges for the future of health. Prevention represents – along with early diagnosis, treatment and improvement of patient’s quality of life – a key phase in managing NCDs, particularly cardiovascular and neoplastic ones. Today, cigarette smoking is the single most widely predictable cause of cardiovascular disease and cancer, and cessation remains one of the most effective interventions to reduce its risk². Numbers reveal more than 8 million deaths caused by smoking-related diseases in 2019³. Smoking can also be deadly for non-smokers: exposure to second-hand smoke is thought to be responsible for almost 1.2 million deaths each year.

¹ World Health Organization (2022), “Invisible number: the true extent of non-communicable diseases and what to do about them”, www.who.int, <https://www.who.int/teams/noncommunicable-diseases/invisible-numbers>

² World Health Organization (2022), *op. cit.*

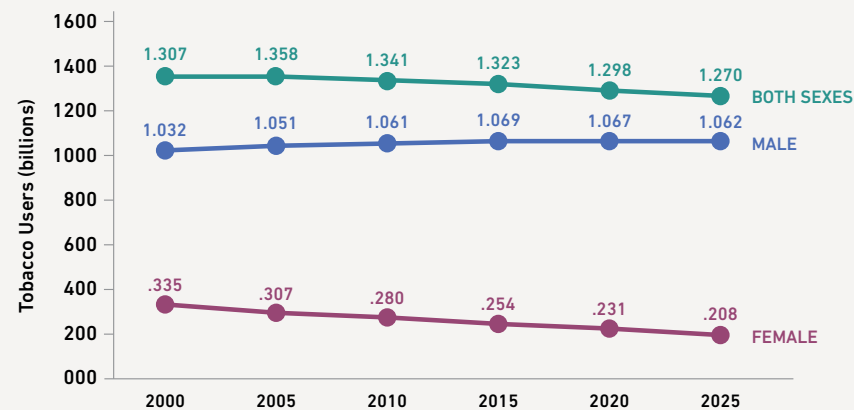
³ World Health Organization (2022), *op. cit.*

The Global Plan of Action of the World Health Organization for the Prevention and Control of Non-Communicable Diseases 2013-2020 includes the goal of reducing the global prevalence of tobacco use by 30 per cent by 2025

The Global Plan of Action of the World Health Organization for the Prevention and Control of Non-Communicable Diseases 2013-2020 includes the goal of reducing the global prevalence of tobacco use by 30 per cent by 2025⁴. WHO proposes that

Member States select actions from the policy options proposed in the Plan. These include proper information to smokers about the dangers related to smoking, to be pursued through effective health warnings and mass communication campaigns; the enactment of legislation to make smoke-free environments in all workplaces, public places, and indoor public transport; the reduction of the affordability of tobacco products and the banning of all forms of advertising, promotion and sponsorship of tobacco.

1•Trends in the global number of tobacco users aged 15 and older



4 World Health Organization (2019), "WHO launches new report on global tobacco use trends", [www.who.int, https://www.who.int/news/item/19-12-2019-who-launches-new-report-on-global-tobacco-use-trends](https://www.who.int/news/item/19-12-2019-who-launches-new-report-on-global-tobacco-use-trends)

For many decades, the main strategy for reducing the harm caused by cigarette smoking has focused on preventing smoking initiation and promoting cessation. However, despite these efforts, the WHO Global Report's series on the prevalence of tobacco use shows that the number of smokers has remained broadly stable over the past 20 years⁵, and that it would take more than 140 years to end the problem if this continued. Only 30% of countries are on track to meet the WHO target of reducing adult smoking prevalence by 30% by 2030⁶. The organisation estimates that there are still more than one billion smokers worldwide. This figure is not likely to fall significantly between now and 2025 due to population growth, which partly offsets the decline in smoking incidence.

5 World Health Organization (2023), "WHO report on the global tobacco epidemic, 2023: protect people from tobacco smoke", [www.who.int, https://www.who.int/publications/i/item/9789240077164](https://www.who.int/publications/i/item/9789240077164)

6 World Health Organization (2019), *op. cit.*

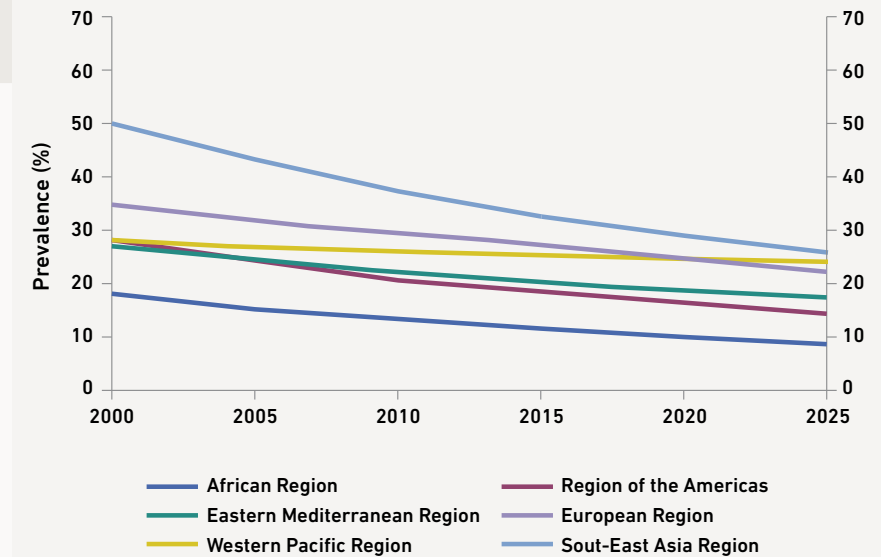
Smoking around the world

In 2023, there will still be 1.3 billion⁷ smokers worldwide. Significant differences exist between regions in an overall picture of a widespread, albeit slow, decline globally. Among the geographical areas identified by the WHO⁸, Southeast Asia shows the most significant decrease in the percentage of smokers, from 50% in 2000 to 29% in 2020. Again, according to the World Health Organization, this is a percentage destined to fall further in 2025, reaching 26%. Conversely, Africa is the region with the absolute lowest percentage of smokers: about 18% of the total population in 2000, declining to only 10% in 2020. Among the macro-areas, the Western Pacific (Far East and Oceania) is the one that has declined more slowly over time than the global average rate of reduction. In fact, the WHO predicts an average relative reduction of only 8% of smokers from 2010-2025 for this region. The European region also shows a relatively slow decrease, with a reduction rate of 19% between 2010 and 2025. The same applies to the Middle East, which shows a smaller decrease in the percentage of smokers compared to the global average rate, from 20.5% in 2015 to 17% in 2025 (Figure 2).

⁷ World Health Organization (2023), "Fact sheets - Tobacco", *www.who.int*, <https://www.who.int/news-room/fact-sheets/detail/tobacco>

⁸ World Health Organization (2023), "WHO Report on the Global Tobacco Epidemic 2021: Addressing New and Emerging Products", *www.who.int*, <https://www.who.int/publications/i/item/9789240032095>

2•Trends in current tobacco use among people aged 15 and older



Looking at country-level data, **China**, with the highest incidence of smokers globally, has an average of 300 million smokers and 2.53 trillion cigarettes sold annually (2020), and it is also the world's largest cigarette producer. China's National Tobacco Corporation is the world's largest tobacco company. China's tobacco monopoly controls about 45% of the global cigarette market, a larger share than all four largest tobacco corporations combined, with an estimated contribution of up to 11% of total Chinese tax revenues. Between 2000 and 2020, the global adult tobacco consumption rate (which includes smokeless tobacco) fell by only 1%.

Approximately 274 million individuals aged 15 years and above smoke in **India**, or 27.2% of all adults, about half the 54.5% in 2000. Despite this, the World Health Organization estimates India is home to 12% of the world's smokers. The import, sale and consumption of electronic cigarettes have been banned in the country since 2019.



Indonesia has approximately 57 million smokers out of a population of 273 million. About 63% of men and 5% of women declare smoking, i.e. 37.6% of the adult population. A figure slightly up from 35.4% in 2000. Alternative products to cigarettes are used by 2.8% of the population.

On the other side of the Pacific, the overall smoking prevalence has declined in **the United States** since 2006, when it stood at 20.8% of the population. This figure is now down to 12.4%. This success is due to information campaigns on the harms of smoking over the years. Concerning electronic cigarettes, the number of vapers in the United States is 9.1 million.

In **Canada**, 13% of citizens aged 15 years and over currently

smoke cigarettes, a sharp decrease from 28.3% in 2000. In 2021, the annual Canadian Tobacco and Nicotine Survey, conducted by the National Health Authorities, reports that 5% of Canadians aged over 15 years declared having used e-cigs and heated tobacco products in the 30 days before the questionnaire.

In **Japan**, 19.4% of the population smokes, with approximately 21 million smokers. The smoking prevalence in the country was 32% in 2000 and has decreased to 21% in 2015. The market share of smoke-free products is now more than a quarter (25.8%) of the mainstream market.

In **Australia**, since 1995, the percentage of adults who smoke daily has decreased from 23.8% to 13.8% in 2017-18.

Smoking in Europe and Italy

At the European level, in 2020, data show a decrease in the incidence of smoking by just two percentage points compared to 2017, showing that the overall smoking rate on the Old Continent stands at 25%⁹. The 2021 Eurobarometer data, i.e. the set of official surveys used by the European Parliament, the European Commission and the other institutions and agencies of the European Union to regularly monitor the state of public opinion, testify that in many Member States, at least one in five people are smokers. However, there are significant differences between the EU Member States¹⁰. In Greece, smokers stand at around 42% of the population, in Bulgaria 38%, in Croatia 36% and in Italy over 20%. At the other end of the spectrum, only 7% of the population in Sweden is a smoker, 12% in the Netherlands and the UK, and 15% in Finland. For the Eurobarometer surveys, respondents were also asked whether they used e-cigarettes and heated tobacco products. The vast majority of EU respondents said they had never used these products. One in seven respondents (14%) said they had tried electronic cigarettes, while only one in twenty (6%) answered about heated tobacco products in the affirmative. By contrast, more than nine out of ten respondents (93%) had never used these products, and only 1% had used them but quit. Less than one in twenty respondents (4%) stated

⁹ World Health Organization (2023), "World Health Statistics", www.who.int, <https://www.who.int/data/gho/publications/world-health-statistics>

¹⁰ European Union (2021), "Eurobarometer", [www.europa.eu](http://europa.eu), <https://europa.eu/eurobarometer/surveys/detail/2240>



that they had tried them once or twice, while a small percentage (1%) currently use them¹¹.

According to the latest survey conducted by the Italian Health Institute, Istituto Superiore di Sanità, in collaboration with the Mario Negri Institute, cigarette smokers in Italy would currently be 20.5% of the population (10.5 million people). Regarding the use of non-combustion products, e-cigarettes and heated tobacco products, the same survey reports that occasional and habitual e-cig users would be 2.5% of the population (equal to 1.3 million). Concerning the so-called Heated Tobacco Products (HTP), they are reportedly used, occasionally and habitually, by 3.7% of the Italian population, approximately 1.9 million people¹².

¹¹ European Union (2021), "Attitudes of Europeans towards tobacco and electronic cigarettes", www.europa.eu, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_342

¹² Istituto Superiore di Sanità (2023), "Press release No. 39/2023 - World No Tobacco Day: data on smokers in Italy", www.iss.it, <https://www.iss.it/-/comunicato-stampa-n%C2%B039/2023-world-tobacco-free-day-one-third-of-teens-%C3%A8-consume-cigarettes-and-cigs-or-take-cigarettes>



The Framework Convention on Tobacco Control (FCTC) of the World Health Organization

Following the awareness of public authorities of the effects of smoking on health since the 1950s, in an increasing number of countries, the need to intervene with policies to combat smoking has increased. However, it was only after the first statutes were introduced in (some states of) the US and some European countries that, in the 1990s, the World Health Organization, which has as its priority objective “achieving the highest attainable standard of health for all”¹³, began negotiations on an agreement to establish an instrument to promote tobacco control interventions at the international level. It was not until 1997 that the World Health Assembly, WHO’s internal decision-making body, decided to proceed with institutionalising the **Framework Convention on Tobacco Control (FCTC)**, which was formally adopted at the WHO Assembly in 2003. Thus was born the first global public health treaty aimed at developing international legislation to combat smoking. Entered into force on 27 February 2005, the Convention “represents the first international treaty for the protection of public health that is legally binding”¹⁴ for the states that are party to it, and its main objective is to establish a global agenda for tobacco regulation to reduce tobacco use. It has been ratified by 182 countries (the last one, in 2020,

¹³ World Health Organization (2023), *www.who.int*, <https://www.who.int/about/what-we-do>

¹⁴ Framework Convention on Tobacco Control (2003), *www.fctc.who.int*, <https://fctc.who.int/publications/item/9241591013>

As the Convention states, tobacco control is defined as: “a range of strategies to reduce the obtainment, demand and harmful effects aimed at improving the health of a population by eliminating and reducing its consumption of tobacco products and its exposure to tobacco smoke”

Andorra). Italy ratified in 2008. The body charged with overseeing the status of implementation of the Convention is the **Conference of the Parties (COP)**, which is composed of delegates from all countries that have ratified the Treaty and is the main decision-making body of the FCTC. The COP, as established by Article 23 of the Convention, performs

tasks of guidance and control of the FCTC by defining its protocols and guidelines and has the power to amend the Convention. The COP then performs monitoring functions for the effective implementation of the Convention by States that have ratified it, facilitates international cooperation initiatives with other organisations or agencies of the United Nations and manages the financial resources of the Convention itself.

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The Convention consists of 38 articles divided into 11 sections and opens with the definition of the objectives, guiding principles and general obligations contained in Articles 1-5 (Sections I and II). Section III, containing Articles 6-14, is devoted to measures to influence the demand side of tobacco consumption. These are mainly based on raising the price of tobacco products and on non-financial measures, demand reduction, reducing exposure to smoking, public education and awareness, and regulating tobacco

¹⁵ Framework Convention on Tobacco Control (2003), *op. cit.*

product composition, information and labelling. On the supply side, the strategy put in place by the Convention looks at combating illicit trade and sales to minors.

Sections V to XI cover topics ranging from environmental protection, responsibility, technical and scientific cooperation and the rules on the exchange of information, right down to the provisions on the operation of the Convention itself.

The articles of the Convention partly define the steps to be taken to achieve the goals set by the parties: over time, the guidelines adopted by the COP, which specify in greater detail the measures to implement the Convention itself, have taken on an increasingly important role. However, the provisions contained therein are not binding on ratifying states of the Convention but are merely acts of guidance for countries that decide to apply regulations, which may go beyond what is stipulated in the Convention. Apart from the articles of the Convention, in fact, only the protocols are binding on states. The only protocol adopted to date is the one on combating the illicit market in cigarettes.

In the twenty years of the FCTC's existence, there have been nine sessions of the Conference of the Parties; the tenth session will take place in November 2023 in Panama. On this occasion, decisions will be made on the regulation of all nicotine-releasing products.

The harm reduction principle

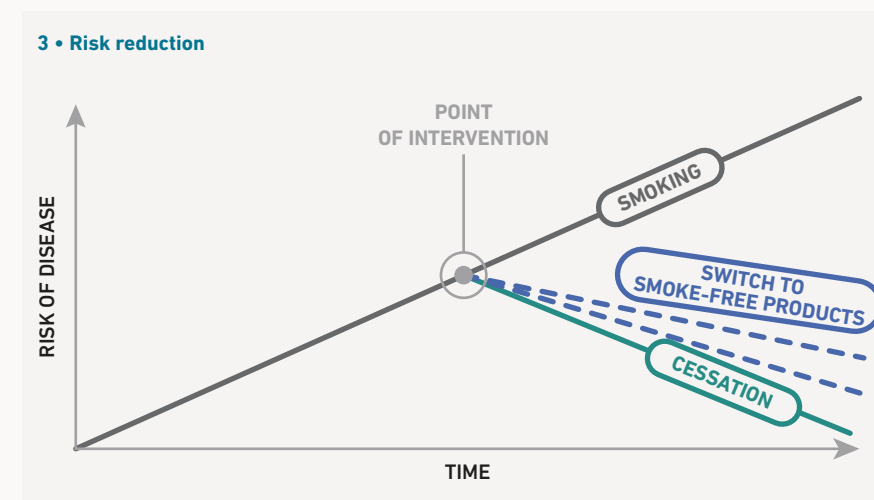
Numbers show that the strategies adopted in recent years have not led to significant improvements in combating the smoking problem in the global population. It is, therefore, necessary to understand how to enhance what has worked in the past years and what have been areas where insufficient action has been taken, such as in the case of prevention policies, while at the same time reflecting on what different measures should be taken. In this context, the debate on risk reduction has become increasingly important. The principle, already applied to alcohol abuse, eating disorders and other addictions, refers generically to interventions to reduce the negative health effects of certain behaviours when these cannot be fully eliminated.

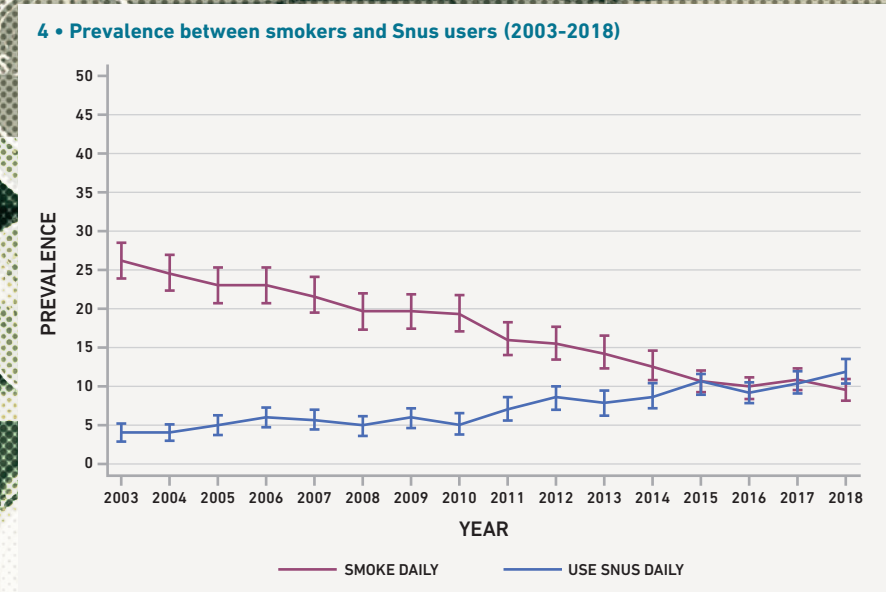
Unlike in the 1980s and 1990s, the implementation of this strategy in the smoking field is now made possible by advances in technology and science, which have made it doable to develop products that release nicotine without combustion. This aspect is central to an effective risk reduction strategy because, as psychiatrist Michael Russell, who pioneered tobacco addiction studies and cessation treatments, said, "People smoke for nicotine, but they die from the tar". Indeed, it is scientifically known that it is the process of burning tobacco and paper that is the main source of emission of toxic or potentially toxic substances that are the cause of smoking-related diseases.

In the case of new products, however, no combustion process takes place, but heating. The separation of the nicotine release process from the combustion process is, not surprisingly, also the basis for the development of medical devices for smoking cessation, such as patches, chewing gum and nasal sprays that contain nicotine, but which, unlike non-combustion products, are aimed at smokers who want to quit.

In contrast, the objective of Tobacco Harm Reduction (THR) aims to accompany those cigarette smokers who do not quit towards a switch to non-combustion products that, while not being risk-free alternatives, aim to reduce exposure to toxic substances.

If cigarette smoking harms the smoker to an exponential risk of developing smoke-related diseases, only not starting and cessation can totally reduce it. The use of alternative smoke-free strategies can, however, take this risk away from smokers as far as possible, bringing it closer to the ideal curve represented by cessation (Figure 3).





The first product to be used for this purpose was Snus, an alternative system to combust tobacco, which was used in Sweden for more than a century. In contrast to other non-combustion products available today, the Snus is not the result of a technological innovation: it consists of small pouches of tobacco powder that are placed under the upper lip, in contact with the gum, allowing the absorption of nicotine.

In 2020, Snus was evaluated by the US Food and Drug Administration, which concluded that: “the use of Snus instead of cigarettes exposes the user to a lower risk of oral cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis”. In Sweden, out of a total population of over 10 million people, the percentage of cancer-related deaths stands at 0.2%, while in other countries, the percentage is much higher. All in all, the marketing of Snus in Sweden and its use as an alternative to traditional tobacco products has contributed to a

record-low prevalence of smoking in the population and the lowest level of smoking-related diseases among men in Europe.

More recently, thanks to technological innovation, other products capable of eliminating combustion have come onto the market. The first are the so-called electronic cigarettes (e-cigs). These are systems powered by rechargeable batteries, which contain an inhalation-activated mechanism that heats up a cartridge tank containing a liquid, producing the vapour inhaled by the device. E-cig liquid generally contains propylene glycol and/or glycerol, with or without nicotine and with or without flavourings.

Subsequently, heated tobacco products were introduced onto the market. These are devices that generate an aerosol containing nicotine but from the controlled heating of particular tobacco sticks. In these systems, the tobacco is heated to temperatures much lower than those needed to trigger combustion (<350 °C).

The opinion of international and national health bodies on non-combustion products

The scientific evidence available to date on alternative products has been evaluated positively by numerous regulatory bodies at the international level. In this regard, dozens of independent scientific studies and analyses have been published. Among the most recent, there is a commentary in *Nature Medicine*¹⁶ (among the world's twenty most respected scientific journals) emphasising the role played by e-cigs in promoting cigarette cessation and reducing smoking-related harm. Particularly relevant is also the systematic review conducted by Cochrane¹⁷, an internationally recognised scientific body, which showed that e-cigs, while not being zero-risk products, can bring long-term benefits to their users¹⁸ compared to cigarettes' consumption, as their aerosol contains up to 95% lower levels of harmful or potentially harmful substances than cigarette smoke. The conclusion of the review is that "there is high certainty that smoking cessation rates are higher in people randomised to the nicotine (e-cigarettes) compared to those randomised to nicotine replacement therapy".

Here are some of the most relevant opinions of international regulatory and health bodies that have spoken out in favour of non-combustion products.

16 *Nature Medicine* no.29 (2023) - Warner, K.E., Benowitz, N.L., McNeill, A. *et al.* "Nicotine e-cigarettes as a tool for smoking cessation", pp. 520-524, <https://doi.org/10.1038/s41591-022-02201-7>

17 *Cochrane Database Syst. Review* (2022) - Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. "Electronic cigarettes for smoking cessation", <https://pubmed.ncbi.nlm.nih.gov/37403047/>

18 *Cochrane Database Syst. Review* (2022), *op. cit.*

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Public Health England stated that e-cigarettes are 95% less harmful than traditional cigarettes. The UK National Health Service reports that "more and more people are turning to vaping to stop smoking. Electronic cigarettes are much less harmful than cigarettes and can help to quit smoking for good.

Many thousands of people in the UK have already quit smoking with the help of an electronic cigarette"¹⁹. Last July, the British Prime Minister, Rishi Sunak, commented that "there is such persuasive evidence that if you can help existing adult smokers to switch away from smoking to using vapes there are clearly public health benefits of acting before the bigger problems come down the line"²⁰.

The **US Federal Food and Drug Administration (FDA)** has provided the introduction of the category "Modified Risk Tobacco Products", a status that can only be obtained after a comprehensive review process of the scientific evidence available on new products. Based on this evidence, the agency determines whether or not a product is appropriate for "protection" or "promotion of public health", taking into account the overall risks and benefits²¹. In 2020, the FDA has authorised the marketing of two devices falling into this category: an electronic tobacco heating system and the Snus oral tobacco, the latter having the status of a "reduced risk" product compared to cigarette smoking. Electronic cigarettes have also been

19 National Health Service (2022), "Using e-cigarettes to stop smoking", www.nhs.uk, <https://www.nhs.uk/live-well/quit-smoking/using-e-cigarettes-to-stop-smoking/>

20 Sandro Iacometti (2023), "Cigarettes, the smoking ban doesn't make you quit", www.liberoquotidiano.it, <https://www.liberoquotidiano.it/news/piulibero/36447198/sigarettes-smoking-ban-don-t-make-youquit.html?upwithpatriots=true#:~:text=The%20same%20First%20Minister%20Rishi,great%2C%20there%20would%20be%20clear%20benefits>

21 U.S. Food and Drug Administration (2023), "Modified Risk Tobacco Products", www.fda.gov, <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products>

granted marketing authorisation (or stay on the market for products that have already been introduced). In October 2021, the FDA announced that it had authorised the marketing of the first electronic cigarette.

In Germany, the **German Federal Institute for Risk Assessment (BfR)** has stated on several occasions that the reduction of emissions from heated tobacco products reduces exposure to toxic substances and potential health risks and that “the profound reduction (>99%) of the main carcinogens, as well as the substantial overall reduction of toxic substances, should affect the risks for health if people abstain completely from other tobacco products. Nicotine levels are similar to those of conventional cigarettes, limiting the risk of returning to smoking traditional tobacco”²².

The Italian **Ministry of Health** in 2018 stated that, due to the scientific evidence available at the time, it was not possible to recognise the reduction of toxic substances in non-combustion compared to combustion products under the same conditions of use and that scientific data do not allow to establish the risk reduction potential for combustion products. The Ministry of Health and the Italian National Institute of Health have repeatedly emphasised that “the risk or harm reduction principle [...] cannot be adopted as a public health strategy, which aims instead at the cessation of smoking and the use of tobacco or nicotine-containing products”²³.

The **Dutch National Institute for Public Health and the Environment (RIVM)** developed a model to compare the impact of the carcinogenicity of tobacco products by comparing heated tobacco products and regular cigarettes. The model examined a range of

22 German Federal Institute for Risk Assessment (2018), “How dangerous are tobacco heaters?”, *www.bfr.bund.de*, https://www.bfr.bund.de/en/press_information/2018/20/how_dangerous_are_tobacco_heaters_-204472.html

23 Rezza G, Ugenti R. (2021), “Ministero Salute: la lotta al fumo non si fa con l'industria del tabacco”, *www.quotidianosanita.it*, https://www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=92594




carcinogenic particles and evaluated their effects on health and the difference between those to which one is exposed when using Heated Tobacco Products and cigarettes. Research shows that exposure of combinations emitted by the two products was found to be 10 to 25 times lower when using HTP instead of cigarettes. The Institute stated that “the use of heated tobacco sticks may be harmful to health, but probably less damaging than cigarette smoking”²⁴.

24 International Web Post, “Fumo, studio olandese confronta impatto cancerogenicità prodotti tabacco”, *www.internationalwebpost.org*, https://www.internationalwebpost.org/contents/Fumo_studio_olandese_confronta_impatto_cancerogenici-t%C3%A0_prodotti_tabacco_17477.html

Risk reduction: international cases

The practical application of the principle of risk reduction concerning smoking has met with increasing favour over the years in various global realities. Not all countries that have applied this principle have done so similarly. Many have believed more in some non-burning products, while others in other kinds. The principle remains the same: convince those who do not quit to leave a burning product for a non-burning product. Many factors, including cultural ones, influence the different strategies countries adopt.

 The Swedish case is emblematic. **Sweden** has been moving towards the total abolition of smoking for decades now. The Swedish end-game strategy is defined with a maximum adult smoking rate of 5%. The country has reached the target set by the EU's European Beating Cancer Plan for 2040 almost seventeen years early, with a reduction in the smoking rate from 15% to 5.6% over the last 15 years. In Sweden, smokers have switched to smokeless alternatives thanks to the oral tobacco Snus, a traditional product with a robust local industry. The marketing of Snus and its use as an alternative to conventional tobacco products have contributed to the record of the lowest smoking prevalence in the population and the lowest level of tobacco-related diseases in Europe. At the European level, Snus is today only legal in Sweden.


 The **UK** is now an international benchmark for risk reduction strategies applied to smoking. The British government was the first

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to incentivise smokers to switch to non-combustion technology products alongside other restrictive policies on traditional cigarettes. The position of Public Health England has already been discussed here: "Based on the evidence examined, we believe that the estimate of at least 95% less damage caused by those using low-

risk products remains largely accurate, at least in the short and medium term".

These statements are confirmed by data from the UK Office for National Statistics, which show that e-cigarettes have significantly reduced smoking rates. In the UK, the prevalence of cigarette smoking fell from 18% in 2014 to 14% in 2020. In 2021, this figure dropped significantly to 13.3% – the lowest percentage of smokers since records began in 2011.

 The **United States** is a clear example of how accepting anti-smoking strategies linked to the principle of risk reduction can bring positive results in combating tobacco addiction. In 2009, the US Food and Drug Administration introduced the category "Modified Risk Tobacco Products", a status granted only when there is clear evidence based on which the agency can determine whether or not a specific product is appropriate for "protection" or "promotion of public health". The institution of the category already represented a political choice in itself, an opening to the possibility that some tobacco products would show a different risk from conventional smoking products over time, thanks to technological progress and scientific research. Although the first marketing authorisations for tobacco products as "modified risk" products date only from 2019, it is also thanks to this pragmatism that smoking figures in

New Zealand is the only country in the world that, after enacting the package of restrictions on smoke-free tobacco products, went back in 2021, implicitly recognising the difference between innovative and traditional products

the United States show a significant decrease, from 20.9% in 2005 to 11.5% in 2021, testifying that the directions taken by the FDA have contributed to a substantial improvement of the smoking prevalence in the population, without any involvement or activation in

the structures of the FCTC.

On the other side of the globe, the case of **New Zealand**, compared with neighbouring Australia, is useful for understanding the effects of accepting or rejecting the principle of harm reduction from smoking in health policies. The New Zealand government has set a robust end-game strategy to make the country completely smoke-free by 2025. To this end, as of 2021, New Zealand has announced the introduction of the so-called Generation Ban, which establishes that all young people born after 1 January 2009 will be banned from purchasing cigarettes. In addition to this ban, the measure includes new restrictions on where tobacco products can be purchased and limits nicotine levels contained in cigarettes. Aware that these solutions alone are insufficient to significantly reduce the smoking rate, the country, as early as 2020, placed harm reduction alongside traditional strategies, recognising the electronic cigarette as a useful tool to help smokers quit²⁵. For this reason, the Generation Ban was not extended to smoke-free products. On the contrary, New Zealand is the only country in the world that, after enacting the package of restrictions on smoke-free tobacco products, went back in 2021, implicitly recognising the difference between innovative and traditional products.

²⁵ Ministry of Health, "Vaping and smokefree history and timelines", www.health.govt.nz/our-work/preventative-health-wellness/smokefree-2025/smokefree-and-vaping-history/va-pin-gand-smokefree-history-and-timelines



Cigarette smoking prevalence in New Zealand in 2014 was close to 16%; by 2021, it had dropped to 9.4%, declining by the 6.5%.

Several significant differences become apparent when comparing the successful case of New Zealand with that of neighbouring **Australia**. In addition to having some of the strictest regulations in the world regarding traditional tobacco, Australia has long since adopted a very restrictive approach regarding electronic cigarettes. These, from 2021, can only be purchased with a doctor's prescription, who will then have to import nicotine liquids from abroad, as the sale of liquids has always been illegal on Australian soil. In this comparison, two diametrically opposed approaches to the principle of harm reduction emerge, which translate in practical terms into different consumption habits of the population²⁶.

As the table below, compiled from World Health Organization data, shows, the prevalence of cigarette smoking in Australia in 2014 was 14%; by 2021, it had dropped to 10.3%, a decline of just 3.7%, making Australia's smoking incidence higher than New Zealand's for the first time.

	2014	2017	2021	Δ%
New Zealand	15,1%	13,3%	9,4%	-6,5%
Australia	14%	13,3%	10,3%	-3,7%

Source: World Health Organization (2021), "WHO report on the global tobacco epidemic 2021: addressing new and emerging products"

²⁶ World Health Organization (2021), 'WHO Report on the Global Tobacco Epidemic 2021: Addressing New and Emerging Products', www.who.int, <https://www.who.int/publications/i/item/9789240032095>

Three cases: China, India and Turkey



In the field of electronic smoking, **China** is one of the countries with the most stringent national regulation. In late 2021, China amended the Tobacco Monopoly Law, including electronic cigarettes. The action meant that vaping products and their manufacturers had to adhere to the strict government regulations that also applied to cigarettes. In addition, electronic cigarettes in China today cannot be sold online or have flavours other than tobacco.

While China continues to prefer the hard line on electronic smoking at home, concerning foreign markets, its philosophy is substantially different. About 90% of global vaping products are in fact manufactured in China. The country's expansion into vaping was made possible by the "New Silk Road", an initiative also applauded by the WHO for "integrating health into its economic partnerships".

To date, the WHO has never criticised China for its role in promoting the consumption of these products abroad, nor for the scale of smoking at home.

On the contrary, despite its world record for the number of smokers, China represents one of the main WHO "models" for anti-smoking policies, with an average score of 7.5 out of 10 for compliance of regulatory instruments with those of the WHO.

Despite its 274 million individual smokers, **India** has also adopted a very restrictive policy on new products, banning the production,



distribution and sale of e-cigarettes and alternative products to combusted tobacco from 2019. The measure clashes with the country's decision to enter the e-smoking business: the production and sale of nicotine, intended for export, is now owned by the company ITC Limited, formerly known as India Tobacco Company, in which the government owns part of the shares. Despite this, the former Indian Health Minister, Harsh Vardhan, in 2021, on World No Tobacco Day, obtained a special recognition from the World Health Organization for "his valuable leadership in accelerating tobacco control efforts in India".

India was not the first country to ban electronic cigarettes. A few months earlier, it was Erdoğan's **Turkey** that had taken the same decision, causing much outcry, considering that the prevalence of

smokers in Turkey is 40.4% among men and 18.2% among women.

Brazil, Venezuela, Mexico, Thailand, Singapore and **Panama** also made similar choices.



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FCTC and risk reduction

In theory, at its genesis, the Framework Convention on Tobacco Control embraced the principle of risk reduction, considering it in Article 1 and defining tobacco control as “a series of strategies to reduce the obtainment, demand and tobacco harm that aim to improve the health of a population by eliminating or reducing tobacco use”²⁷. More recently, in 2015, the WHO stated that “the development of new tobacco products that are less toxic or addictive could be one component of a comprehensive approach for reducing tobacco-related deaths and illnesses, particularly among tobacco users who are unwilling or unable to stop their addiction”. In recent years, however, the orientation of the WHO and the FCTC has changed radically, going so far as to promote a total equation between cigarettes and combustion-free products, suggesting that the Parties to the Convention regulate them as combustible cigarettes or even ban their production, marketing, import and export, even though the WHO itself recognises that they reduce exposure to harmful substances compared to traditional cigarettes.

In fact, in its recent report, “Comprehensive report on research and evidence on novel and emerging tobacco products”, the organisation states that “independent studies show that the temperatures reached by heated tobacco products are not sufficient

²⁷ Framework Convention on Tobacco Control (2003), *op. cit.*

In 2015, the WHO stated that “the development of new tobacco products that are less toxic or addictive could be one component of a comprehensive approach for reducing tobacco-related deaths and illnesses

to give rise to combustion” and that many toxic substances present in combusted tobacco are “present at significantly lower levels in HTP’s aerosol”. In the same report, among the evidence that would justify equalising non-combustion products with

traditional products, the WHO mentions that “damage to cells and genetic material is more significant after exposure to HTP aerosols than after exposure to air”²⁸. The Organisation seems focused on evidence that new products maintain an absolute risk profile rather than determining their relative risk, i.e. compared to cigarettes. The Organisation’s recommendations suggest increasingly restrictive regulation of smoke-free products, equating them with cigarettes despite evidence of reduced toxicity and even though the vast majority of smokers worldwide still smoke conventional cigarettes (according to Eurostat data, only 2% smoke e-cigs), with no substantial signs of decline. The WHO has historically supported interventions and approaches to public health policies aimed at harm reduction when they have been directed at combating harmful behaviours such as alcohol abuse and drug use. However, despite the scientific evidence, while recognising nicotine as an addiction, declaring it as a “severe addiction” affecting over one billion of people worldwide, the WHO does not seem to want to apply this principle in the fight against smoking.

²⁸ World Health Organization (2021), “Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products, in response to paragraphs 2(a)-(d) of decision FCTC/COP8(22): report by the World Health Organization”, www.who.int, <https://apps.who.int/iris/handle/10665/368624>

The debate on non-combustion products in Italy and abroad

“Despite the evidence that vaping and non-smoking products significantly reduce risk and harm, the aggressive marketing of big tobacco companies has produced other harm. Manufacturers have invaded the holy territories of science and its representatives by directly contacting scientific societies, supporting conferences, and defending the new era of harm reduction; this has alarmed those who have always followed smoking and the health sectors. Even though it is clear that if all smokers switched to electronic, we would see a fall in the incidence and prevalence of many cancers, vapers are no longer seen as instruments of harm reduction, but as marketing tools”²⁹.

The words of Professor **Giacomo Mangiaracina**, specialist in Public Health, lecturer in the Faculty of Medicine and Psychology at Rome’s Sapienza University, and President of the National Agency for Prevention, explain as concisely as explicitly what almost always remains between the lines in the debate on smoke-free products: according to a significant part of the medical-scientific community, even before an evaluation of the science of smoke-free products, it is the very presence of the tobacco industry that precludes any possibility of dialogue. In other words, since the industry markets the new non-combustion products and the industry conducts scientific

²⁹ Formiche and Healthcare Policy (2022), Il Futuro delle policy sul fumo tra prevenzione e riduzione del danno

The appearance of alternative products to combusted tobacco has fuelled a strong contrast between those who emphasise that the scientific evidence is not yet sufficient and those who see in these products a significant opportunity

research on such products, the medical-scientific community must reject any claims from it.

The tobacco industry’s responsibility for its perceived trustworthiness is clear. It is based on the second half of the last century, when the debate on

the harmfulness of cigarette smoking met with many obstacles, especially from industry, to see the now scientifically proven truth that smoking is the leading cause of avoidable death on the planet attained. However, if it is true, as Professor Mangiaracina states, that “it is evident that non-combustion products greatly reduce risk and harm”, the result of an a priori rejection of the opportunities now made available by science and technology can only be a vicious circle that does not make an objective comparison on the science, with the risk that this contrast leaves smokers without information on the different degree of risk of non-combustion products. It is a lack that inevitably affects awareness and knowledge, two prerequisites for more informed choices and which can have enormous impacts on public health.

Since their introduction on the market, the arrival of alternative products to combusted tobacco has fuelled, even within the medical-scientific community and policy-makers, a highly polarised debate, with a strong contrast between those who emphasise that the scientific evidence is not yet sufficient to provide a complete picture of their risk profile, and those who see in these products an important tool to complement existing smoking prevention and control policies, precisely to provide smokers who do not quit with an alternative with a potentially different risk profile.

The WHO’s closed position on the subject has already been widely discussed. What should be noted is that this position appears to

Polosa (University of Catania): “If we want to achieve an important public health goal, on the one hand, we must tighten policies against traditional smoking. On the other hand, we need to promote combustion-free alternatives as harm-reduction tools”

be challenged neither in light of the growing available scientific evidence nor in the light of the openness of authoritative public health bodies at the international level nor of repeated calls from public health experts worldwide.

Last November, one hundred scientists, doctors and experts in the field wrote a letter to the member countries of the Framework Convention on Tobacco Control to call for a renewed approach to tobacco policies to recognise that “smoke-free” products are less harmful than traditional cigarettes. The signatories argued at the time that although there is still uncertainty about the benefits and long-term risks associated with combustion-free tobacco products and that there is likely to be a continuum of risk in these alternatives to traditional cigarettes, it is necessary to consider the available evidence and not allow excessive caution or residual uncertainty to deny smokers viable options to abandon combustion products that we know with certainty to be lethal. “Unfortunately,” the petitioners point out, “the WHO has had little regard for the desirability of turning the tobacco market from high-risk to low-risk products. The World Health Organization is discarding a public health strategy that could prevent millions of smoking-related deaths”, they argued. In the letter, the experts point out a vital issue in the relationship between scientific evidence and health policy choices: “Parties to the FCTC should not be distracted from the significant public health potential of reduced-risk products simply because tobacco companies produce them. Harm reduction approaches inevitably involve products made by commercial entities that produce nicotine-containing products for consumers in competition with cigarettes”.

At the Italian level, among the most convinced supporters of the

principle of risk reduction is **Riccardo Polosa**, professor of Internal Medicine at the University of Catania and founder of CoEHAR, Centre for Research on Smoking Harm Reduction, according to which “Scientific evidence amply demonstrates that the use of alternative products drastically reduces the incidence of smoking-related disease deaths, and this has also been well understood by millions and millions of users worldwide who have noticed an improvement in their health by giving up traditional cigarettes. The CoEHAR studies”, Polosa continues, “have shown that combustion-free products are up to 95% less toxic than conventional cigarettes. In the Italian case, it would be important that the application of the harm reduction principle complements public health policies. If we want to achieve an important public health goal, on the one hand, we must tighten policies against traditional smoking. On the other hand, we need to promote combustion-free alternatives as harm-reduction tools, as they are already doing in England and Japan”, the professor concludes.

On the opposite side, **Giulia Veronesi**, professor at the University Vita-Salute San Raffaele and Director of the Strategic Thoracic Robotic Surgery Programme at the IRCCS Ospedale San Raffaele stated in an interview with Formiche that: “The independent scientific literature (consequently, World Health Organization, National Institute of Health - Istituto Superiore di Sanità, Ministry of Health) does not endorse alternative products either because

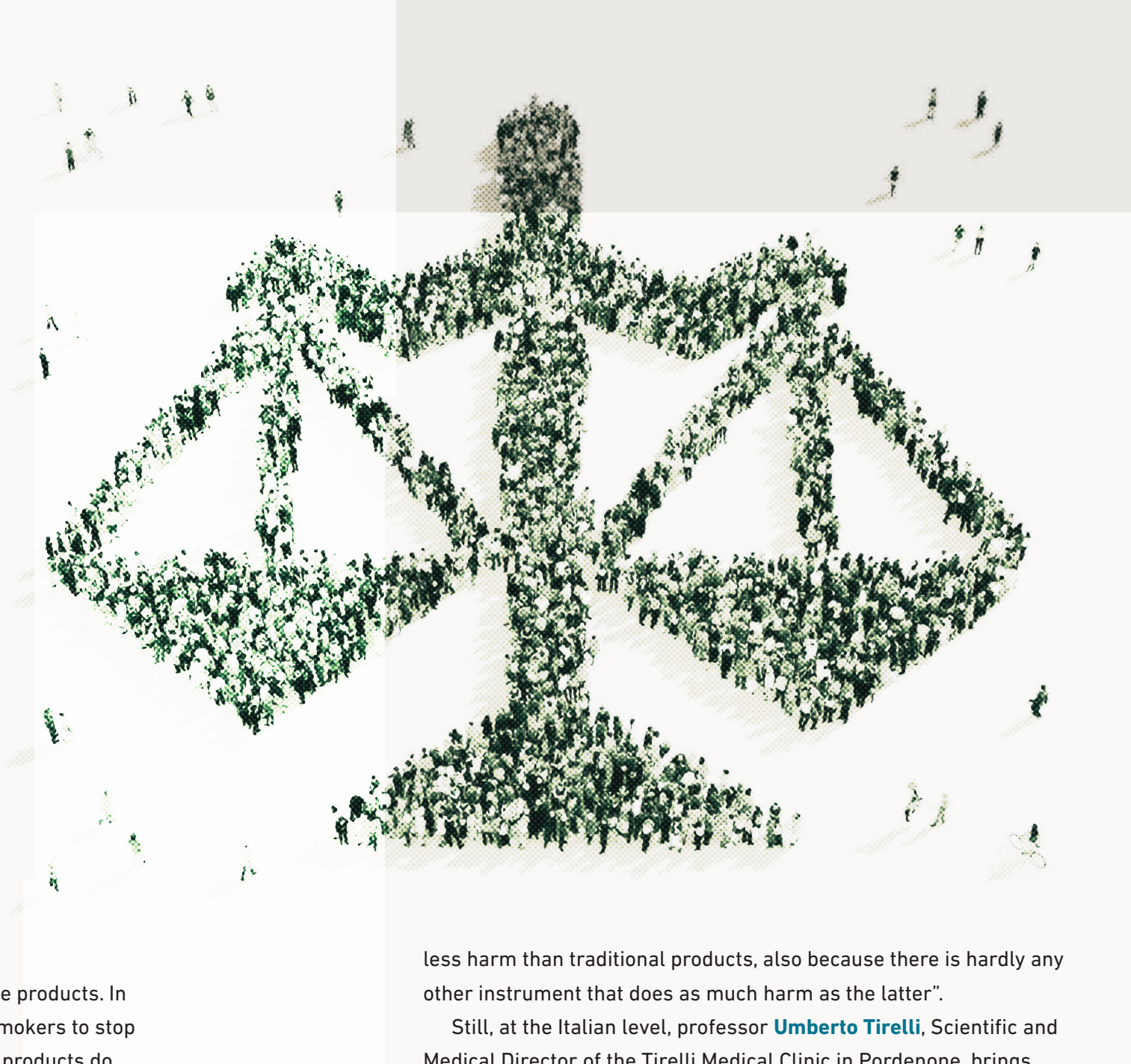
of uncertainty about the health effects considering that some toxic substances present in heated tobacco are not present in traditional cigarettes either from the perspective of harm reduction or because nicotine is highly harmful in young people due to intense

Veronesi (University Vita-Salute San Raffaele): “Perhaps not everyone is aware that the fans of heated tobacco products are those who have agreed to come to terms with the tobacco industry”

addiction as well as certain cardiovascular effects, including promoting the formation of atherosclerotic plaque. Perhaps not everyone is aware that the fans of heated tobacco products are those who have agreed to come to terms with the tobacco industry. The tobacco industry makes hundreds of millions of euros available to those willing to accept funding to study their products. According to independent tobacco control experts, accepting funding from the tobacco industry is considered disreputable, so much so that many who receive this funding do not declare conflicts of interest and/or pretend not to know that the money comes from the tobacco industry”, Veronesi points out. “Furthermore”, says the professor, “it seems that these products do not appeal to ‘heavy smokers’, those who cannot quit by other means and who could theoretically benefit from a less harmful outcome.

Dr. **Silvano Gallus**, Head of the Laboratory of the Department of Medical Epidemiological Research at the Mario Negri Institute, agrees, and in a recent interview³⁰, he states that: “there is no debate on this issue; the tobacco industry creates it. All independent research has already rejected these products. In real life, there is no way that these products enable smokers to stop smoking. However, Gallus himself claims that: “these products do

30 Nidi A. (2021), “Fumo passivo, +51% rischio tumore orale/ Lo studio: tabacco pericoloso”, *www.ilsussidiario.net*, <https://www.ilsussidiario.net/news/fumo-passivo-51-rischio-tumore-oralethe-study-tobacco-dangerous/2162182/>



less harm than traditional products, also because there is hardly any other instrument that does as much harm as the latter”.

Still, at the Italian level, professor **Umberto Tirelli**, Scientific and Medical Director of the Tirelli Medical Clinic in Pordenone, brings the example of Sweden, arguing the need not to deny smokers less lethal alternatives to traditional smoking. For Tirelli: “Mere adherence to the precautionary principle puts the health of so many

Tirelli (Tirelli Medical Clinic): “Sweden is a striking example. The benefits related to the use of alternative products are directly related to a reduction in chronic lung disease: the nicotine is not the cause of this type of disease, but it is combustion”

at risk because, and the example of Sweden is striking, the benefits related to the use of alternative products are directly related to a reduction in chronic lung disease: the nicotine is not the cause of this type of disease, but it is combustion”. “In Sweden”, the professor continues, “a very high proportion of

the male population uses Snus, the tobacco powder for oral use. It is evident that in the country, the share of lung cancer among men is among the lowest in the world [...]. Sweden is a successful example of how alternatives to traditional cigarettes bring tangible benefits to public health. The world will pay for the international wait-and-see attitude in realising that the precautionary principle alone will not save us from smoking-related deaths”, professor Tirelli concludes.

According to **Ben Youdan**, director of Youdan Consulting and advisor to ASH - Action for Smokefree 2025, who spoke last year at The E-Cigarette Summit USA on the case of New Zealand: “This legislation is evident. It helps those who want to give up traditional smoking but also want to avoid encouraging young people towards new electronic devices”. On the other hand, Youdan continues: “It is true that encouraging low-risk products can theoretically bring young people to vaping, but if we look at the data, the prevalence of these new ‘vapers’ shows that only 3% had never smoked, while almost 80% were already regular smokers”. From the most recent edition of the same Summit, which took place last May in Washington, comes a new alarm about the stubborn and contrary direction that the Conference of the Parties of the WHO already seems to be taking by equating innovative products with traditional ones. According to **David T. Swenor**, professor and chairman of the Advisory Board of the Centre for Health Law, Policy and Ethics

at the University of Ottawa: “The meetings of the Conference of the Parties have become an exercise in replicating failed international protocols. They mostly consist of people with little understanding of the dynamics at play or who pursue an agenda other than the pragmatic pursuit of public health benefits”. “Unlike conferences on other issues such as climate change”, Swenor continues, “the FCTC COP is not open to observers. This secrecy precludes scrutiny, informed debate and redirection of efforts in far more effective ways. In the age of the Internet, social media and massive cross-border trade in goods, the ability of people to learn about and access low-cost alternatives to cigarettes cannot be stopped. But the credibility of those who perpetuate the cigarette epidemic by opposing this technology will eventually be destroyed, and they will go down in history as at least as guilty as the cigarette companies in causing death and disease”, Swenor adds.

In the same forum and on the same subject, American professor **Clifford E. Douglas**, Director of the Tobacco Research Network at the University of Michigan, among the signatories of the 100 experts’ letter mentioned above, says: “WHO and FCTC continue to maintain a very traditional approach that seeks to dismiss the principle of harm reduction totally and, if this approach continued, it would be

Swenor (University of Ottawa): “The meetings of the Conference of the Parties have become an exercise in replicating failed international protocols. They mostly consist of people with little understanding of the dynamics at play or who pursue an agenda other than the pragmatic pursuit of public health benefits”

a problem for the global public health framework”. Once again, the reason for these hesitations would coincide with a deep distrust in the tobacco industry: “A war seems to be emerging between good guys and bad guys, where the tobacco industry represents the bad guys. What this conflict produces is a deprivation of science. As stated by many scientists worldwide, the WHO

Douglas (University of Michigan): “WHO and FCTC continue to maintain a very traditional approach that seeks to dismiss the principle of harm reduction totally and, if this approach continued, it would be a problem for the global public health framework”

has taken misleading and erroneous positions on alternative tobacco products and their potential to save tens of millions of lives”, the professor concludes.

Clive Bates, director of Counterfactual Consulting Ltd, a consulting firm and public health

advocacy, is also of the same opinion: “Unfortunately, I believe the WHO is determined to fight its war on harm reduction by continuing to argue that vaping and heated tobacco devices Heat Not Burn (HNB), should be regulated like traditional tobacco products, i.e. by banning them. This is an approach devoid of any evidence”, argues Bates. A particularly negative consequence of this approach, according to the expert, would be that, unfortunately, many developing countries following this line would continue to make traditional cigarettes available, with disastrous effects on national public health (we have already seen this happen, for example, in China, India, and Turkey). “The next COP will certainly promote an approach that is more widely shared by the various Party countries, but it will be an approach that continues to normalise prohibition and over-regulation of alternative tobacco products, which are by all accounts safer”, says Clive Bates.

According to **Mitch Zeller**, former director of the US Food and Drug Administration’s Center for Tobacco Products, whose fundamentally different orientation towards the harm reduction principle has already been widely discussed: “The FCTC has a conservative view of the health benefits associated with any tobacco product”. The tools that make the US market and the overall public health balance well-functioning concerning reduced-risk products are to be found in specific procedures such as the PMTA (Premarket

Tobacco Product Application) and the already mentioned MRTPA (Modified Risk Tobacco Product Application), which provide for companies to submit requests for an assessment of their products before they are placed on the market, including for an evaluation of their different risk profiles. “The key to the functioning of this mechanism, which makes the United States different from all other countries, many of which are also members of the FCTC, is that the burden of scientifically and accurately demonstrating their role in protecting the public health of citizens falls on the companies. In a justly regulated tobacco environment, where the burden of proof of reduced risk or exposure to smoking falls on the companies, there is room for alternative products. But the key is a justly regulated market for these products, and the US, not being part of the FCTC, has managed to create that with the right regulatory tools. Many member countries do not have the same regulatory framework, which explains the conservative approach they continue to have when it comes to modified risk products”, Zeller concludes.

According to **Peter Hajek**, Professor of Clinical Psychology and Director of the Tobacco Dependence Research Unit of the Wolfson Institute of Public Health at Queen Mary University of London, misinformation is another part of this hostility. “At the moment, the biggest issue concerns the misinformation. The public believes that

Hajek (Queen Mary University of London): “At the moment, the biggest issue concerns the misinformation. The public believes that tobacco alternatives are as dangerous as traditional cigarettes when they are much less dangerous”

tobacco alternatives are as dangerous as traditional cigarettes when they are much less dangerous, and people should be encouraged to use those less risky alternatives. As a result of this posture, which goes against any proper public health strategy, [WHO] will continue to suffer great reputational damage”.

The position of consumers

A recent survey entitled “Italian smokers: habits, opinions and trends”, conducted by the Eurispes Research Institute on a sample of 1018 adult smokers, is useful to detect the orientation of Italian consumers on the subject. The Eurispes survey reveals that 69.1% of respondents agree that the state should promote information campaigns on non-combustion products. 41.5% also agree that the state should encourage studies to evaluate the effectiveness of these products compared to traditional combustion products and their impact on individual health. In comparison, only 12.7% believe that the state should discourage the development of innovative products because there is no possibility of reducing the risk of smoking. In the Italy 2022 Report, it is again Eurispes that proposes a survey on heated tobacco and vaping, from which further indications emerge. Among these, of particular value is the link between the consumption of the new products and the decrease in cigarette smoking or even, in appreciable percentages, the cessation of traditional smoking. According to Eurispes, there is a marked substitution of new products for cigarettes, with 95.7% of the respondents claiming to have previously smoked traditional cigarettes. In comparison, 81.5% of the users claim to have stopped using cigarettes, which is significant given the proportion of smokers who have never tried to quit smoking (62%). While maintaining the necessary attention to the precautionary principle that informs

In two public consultations promoted by the European Commission, European citizens, particularly those in Italy, express the need for clear information on alternatives to cigarette smoking, in which they find essential support for giving up cigarette smoking

health institutions, according to Eurispes, these should open up to risk reduction. At the European level, in 2022 and 2023, the Commission launched two different public consultations because of the upcoming updated legislation on tobacco products. The public consultations promoted by the

European Union have had considerable results in terms of interest in citizens, collecting a total of more than 40,000 comments reporting consumers’ direct experience with combustion-free products, particularly for the replacement of cigarettes. In both consultations, Italy came second regarding the number of responses provided. European citizens, particularly those in Italy, express the need for clear information on alternatives to cigarette smoking, in which they find essential support for giving up cigarette smoking³¹. At the same time, the respondents called on the institutions to make every effort to prevent new products from falling into the hands of the wrong groups, particularly young people and nonsmokers.

³¹ European Commission (2023), “Evaluation of the legislative framework for tobacco control”, [www.ec.europa.eu](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en), https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en Un recente sondaggio dal titolo “I fumatori italiani: abitudini, opinioni



The democratic nature of international law and the FCTC

The management of international affairs is traditionally delegated to the executive power in most countries. Parliamentary influence on concluded treaties is normally relegated to ratifying acts signed by the government and its delegates. This custom, translated into Italian constitutional law through Article 80 of the Constitution, allows the Italian government to send delegations of technicians, usually ministerial managers, to sit at the tables of numerous international debates on behalf of the country. While it is true that international organisations often discuss particular topics, which require specialised negotiators, the legislative power in individual states has increasingly lost the power to oversee negotiations, which are now left entirely to technical bodies, depriving the legitimate representatives of the people of the ability to determine the commitments that the country is about to make.

In this sense, sending delegates of supranational organisations, such as the EU, to international conventions has created a precedent whereby an organisation with indirectly elected leaders can send negotiators (unelected technicians, by definition) and enter into agreements that are binding on the governments and parliaments (these, yes, elected), of its Member States. In the European case, it is illustrative how, given the absence of explicit provisions in the founding treaties of the Union giving it the authority to regulate public health, the EU has, over the years,

As tobacco control issues such as cross-border trade, communication and smuggling make part of the common market, the EU has emerged as an essential political player not only as a regulator of issues between Member States and globally through its direct participation in the FCTC

evolutionarily acquired this authority. As tobacco control issues such as cross-border trade, communication and smuggling make part of the common market, the EU has emerged as an essential political player not only as a regulator of issues between Member States and globally through its direct participation in the FCTC.

Since 2005, the EU has ratified the FCTC and is directly involved in the negotiations. However, it is clear that the commitments bind its Member States in some way in future legislation, regardless of the positions expressed by individual nations in the negotiations.

As far as the coherence between the law in force in the respective countries and the burdens they will bear as a result of ratifying the treaties and which will have an impact on them (think, for example, of the commitments made in the automotive or energy sectors), then we can think of a severe democratic breach affecting the Convention and the participation of EU bodies in it.

This deficiency is disadvantageous for directly elected national bodies (in the Italian case, the two branches of parliament), which find themselves having to ratify, often with perceived urgency, treaties on the content of which they had no say but which they have to justify to their citizens when transposing. This would be fine if the position of the countries were an expression of prior discussion with Parliament and with the various ministries involved in a dossier in a logic of a governmental approach to issues that impact health, the economy and employment. The reality, on the other hand, is that the position taken by the Member States is almost always the result of the work expressed by the reference technician, almost always without even prior coordination with the political leadership of the

ministry concerned and without any involvement of Parliament and the other ministries. On the contrary, often in open contrast with them. The COP10 of the FCTC will be held in Panama in November 2023, for example, aims to equalise the regulatory and tax treatment of new products with that of cigarettes, even though almost all Member States, including Italy, have regulatory frameworks that instead differentiate between combustion and non-combustion products.

In the case of taxation, even the treaties prohibit the EU from legislating on direct tax, which remains the exclusive competence of the individual states, particularly the ministries of the economy. At the COP, on the other hand, representatives of the health ministries will mainly be present, who will, therefore, make decisions on matters that are not within their direct competence but will then make them binding on the member states. It will then be up to the government and parliament to explain to citizens why decisions were taken without their involvement.

Conclusions COP 10: what prospectives?

Non-communicable diseases are the leading cause of death worldwide, and smoking is the main risk factor for these diseases. An estimated 8 million deaths worldwide per year are attributable to smoking. In addition to the health

and social damage, severe smoking-related diseases result in substantial health costs for public budgets. Therefore, when it comes to smoking, there is little doubt that the best thing to do remains, and will always remain, not to start or to quit. Unfortunately, however, as WHO figures show, despite decades of awareness of the harm, many smokers do not stop. It is a difficult habit to quit for more than a billion people worldwide, and the number is falling only very slowly. At this rate, it would take almost a century to eradicate this phenomenon, an eternity that the health, economic and social systems cannot afford. Despite the damage caused by smoking, too little is said about this topic and, almost always, out of bias. In a world characterised by ideological clashes,



Due to scientific evidence on the damage of combustion, research and technological innovation have developed and launched technological products on the market that can release nicotine, the substance smokers are addicted to, but without combustion

the one on smoking is undoubtedly among the most bitter between industry and health bodies and within the scientific community itself. *Politico* spoke of a kind of *conventio ad axcludendum* of science and scientists themselves conducting research with

industry funding, regardless of the robustness of the study, the validity of the data and the prospects it opens up for policies more effective health care³². One wonders what would happen if the same approach were applied to medicine, considering that 85% of research is financed by industry. In this clash, the only one not questioned is the protagonist of this story: the smoker.

This is why we thought it was interesting, on the occasion of the 20th anniversary of the Framework Convention on Tobacco Control established by the WHO – the first public health convention to which 180 countries adhere – to take a closer look at the subject, trying to provide an overview of the state of smoking in Italy and worldwide, and of regulatory developments, the results achieved, the transformation of the sector following the market entry of non-combustion products and the scientific debate on the subject.

Over the past twenty years, many countries have stepped up their anti-smoking policies. Although they have contributed to reducing the incidence of smoking, data show that their momentum seems to have come to a rest.

Faced with this situation, we need to start again from what has worked and understand what new and different things can be done to speed up the end of smoking, starting with prevention and cessation, but also looking at technological evolution. As in so many sectors,

³² Ashleigh Furlong (2023), Inside the toxic world of vaping scientists, www.politico.eu, <https://www.politico.eu/article/aggression-ridicule-bullying-inside-the-world-of-e-cigarette-scientists/>

the last twenty years have seen an incredible evolution in tobacco compared to previous centuries. Due to scientific evidence on the damage of combustion, research and technological innovation have developed and launched technological products on the market that can release nicotine, the substance smokers are addicted to, but without combustion. These products were created to provide precisely those smokers who do not quit with an alternative to continuing to smoke cigarettes in a logic of risk reduction. It is a principle applied in many fields of medicine and embraced by the World Health Organization itself to solve health crises in the recent past. A principle that recurs in the definition of tobacco control adopted in the Framework Convention On Tobacco Control as a complementary measure to prevent and control policies. Yet, ever since these products were introduced onto the market – in many cases by the cigarette companies themselves – a very heated debate has arisen between those who see these products as part of the solution to the smoking problem and those who make no distinction with cigarettes, or who, on the contrary, believe that they should be banned.

Regardless of the scientific evidence and the prospects the alternatives to tobacco open up for speeding up the fight against smoking, these products are opposed by many because they were developed and produced by those who caused the problem. Thus,

Many countries (Sweden, the UK, New Zealand, the USA, Greece, and Canada) have updated their anti-smoking policies to include differentiated regulations between cigarettes and smoke-free products. The data show that these countries are the best performers in decreasing the incidence of smoking

the fight against smoking risks turning into a fight against industry without any progress in public health. Those who support these products claim that, although they are not risk-free, data show that, compared to cigarettes, they significantly reduce toxic or potentially toxic substances and decrease smokers' exposure to them. A fact that, in part,

The preparatory documents for the 10th Conference of the Parties to the Convention state that although the science available to date shows that combustion-free products reduce the toxic substances and exposure of smokers since these products cannot be compared to “air”, they are not an alternative to cigarettes and must be treated in the same way, effectively shutting down scientific research and technological innovation in this field

is also recognised by the WHO itself. Given this evidence, many countries (Sweden, the UK, New Zealand, USA, Greece, Canada) have updated their anti-smoking policies to include differentiated regulations between cigarettes and smoke-free products. The data show that these countries are the best performers in decreasing the incidence of smoking and are likely to be the first to reach the WHO target of a smoking incidence below 5% of the

population. The most emblematic case is Sweden. Those who argue against these products point out that they are dangerous for non-smokers – a potential gateway to nicotine addiction – and are still harmful to health as they do not eliminate toxic substances. This second thesis tends to focus on the absolute risk of the products and not on the relative risk, avoiding comparison with cigarettes.

Furthermore, the view is that they would represent another industry business strategy. So, it is not a transformation towards a more sustainable future but a desperate attempt not to disappear. This thought has been taken on board by the WHO, which, while at first opening the door to the opportunity represented by these products and the application of the principle of risk reduction, has over the years completely reversed its position, going so far as to demand equating the new products with cigarettes or even their total ban. A measure applied in countries such as India, Turkey, Venezuela and Brazil, which, however, do not ban the sale of cigarettes despite having one of the highest smoking rates in the world.

As this issue comes out, the WHO has recently published its preparatory documents for the 10th Conference of the Parties to the

Convention – the body responsible for making decisions at which the Convention countries must comply – which state that although the science available to date shows that combustion-free products reduce the toxic substances and exposure of smokers, since these products cannot be compared to “air”, they are not an alternative to cigarettes and must be treated in the same way, effectively shutting down scientific research and technological innovation in this field. Although inconclusive, the scientific evidence available to date, and the positive experiences of countries that have applied this principle would suggest a more open approach so as not to close an opportunity for smokers who, despite cessation policies, do not quit. As mentioned above, these are not risk-free products; they are not the best choice, but they are probably better than cigarettes. Of course, like all unfamiliar products, primarily if technological, they pose concerns and questions, mainly related to use among young people. These are issues that still need to be investigated and deepened.

In conclusion, we must continue to invest in scientific research to find as many answers as possible. Banning alternatives to tobacco would mean looking the other way, favouring a status quo dominated by cigarettes and encouraging illicit trade. This scenario is happening in countries that have decided to ban them. It would mean precluding the possibility of a choice for smokers.

Insisting on prohibiting alternatives to tobacco would mean looking the other way, favouring a status quo dominated by cigarettes and encouraging illicit trade. This scenario is happening in countries that have decided to ban them. It would mean precluding the possibility of a choice for smokers

The hope is that the forthcoming Conference of the Parties can represent an opportunity for public health but also, in the spirit of the United Nations, a moment of confrontation to guide policy choices based on established scientific evidence. Banning a product because it is not comparable to “air” does not seem to be going in this direction.

