

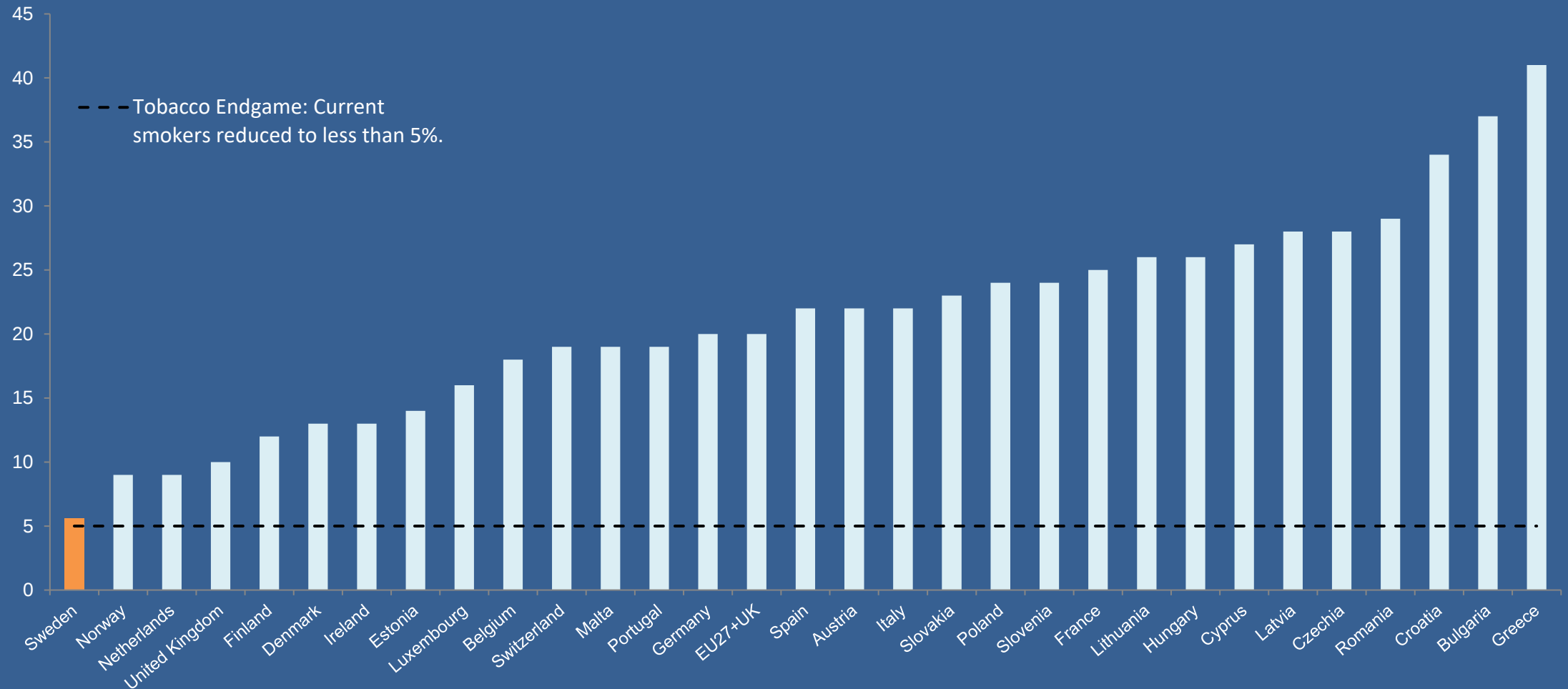
Smokefree nicotine products
and the Swedish example and
its implications for the German
tobacco policy..

Karl Fagerstrom Ph.D.

Relevant Disclosure:

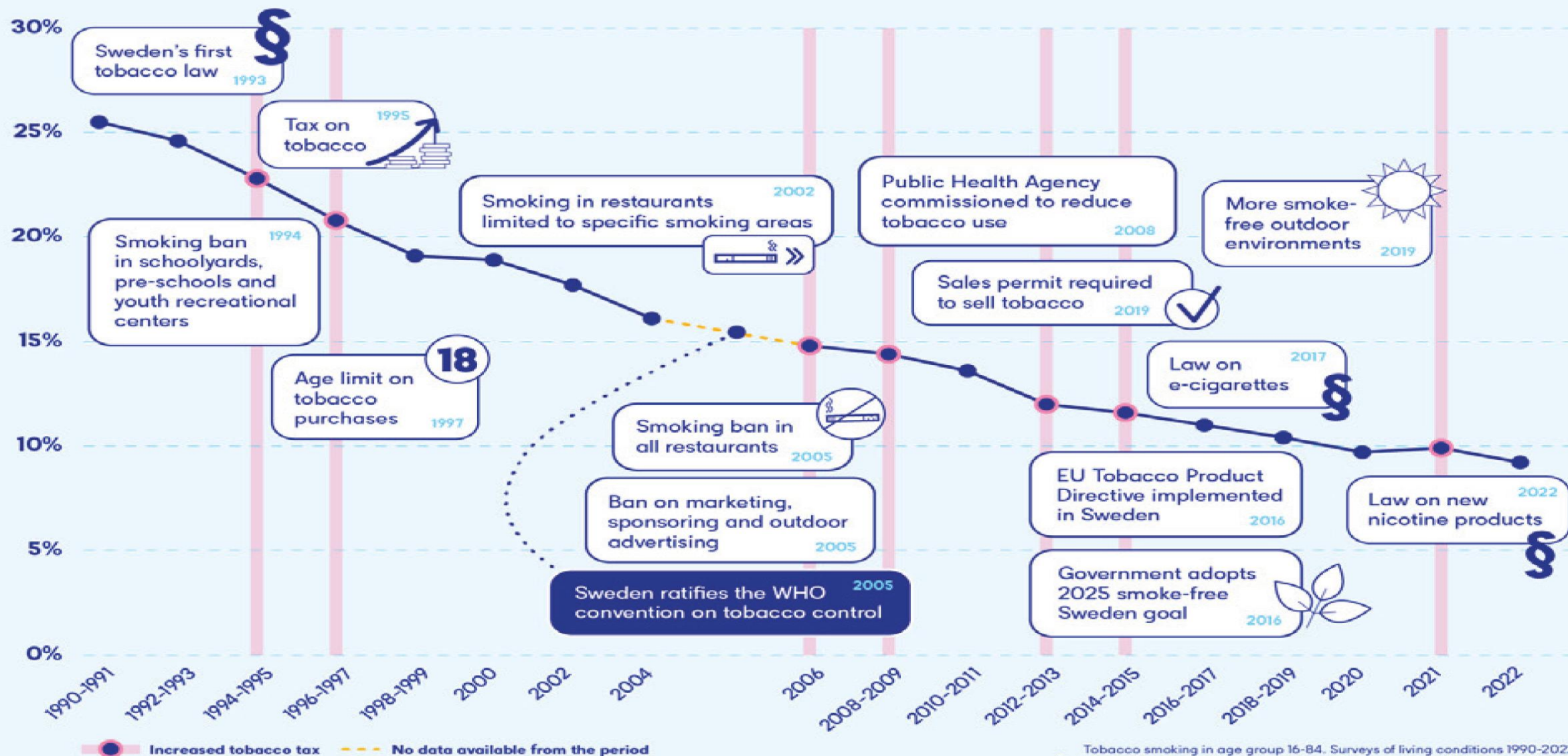
I have received consulting fees from many companies that develop or market pharmaceutical and behavioral treatments for smoking cessation. In the year 2000, I started a company Nicovum that developed the first non-tobacco nicotine pouch that was licensed as a nicotine replacement therapy. I have received fees in the past from Swedish Match and PMP to assist their development of reduced-risk tobacco products.

Prevalence of daily tobacco smokers



Source: Special Eurobarometer 506, Attitudes of Europeans towards tobacco and electronic cigarettes

Policy measures to reduce smoking in Sweden.



Tobacco smoking in age group 16-84. Surveys of living conditions 1990-2022: Statistics on Income and Living Conditions (SILC) conducted by Statistics Sweden

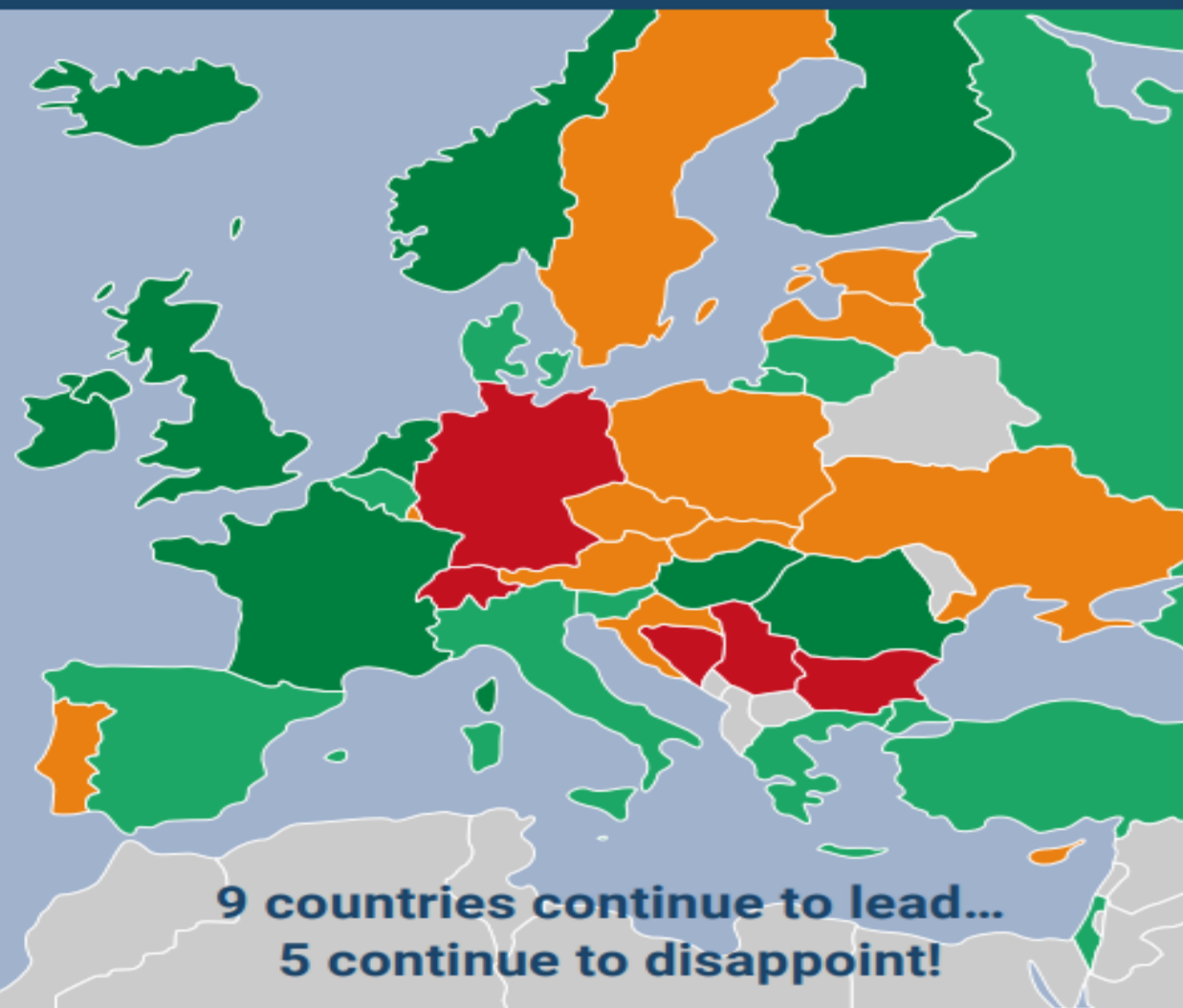
How does your country rate on tobacco control?

2021 Rank	Country		2019 Rank	Score
1	Ireland	▲	3	82
1	UK	—	1	82
3	France	▼	2	71
4	Netherlands	▲	14	67
5	Hungary	▲	8	65
6	Norway	▼	5	63
7	Finland	▼	6	62
8	Iceland	▼	4	61
8	Romania	▲	12	61
10	Belgium	—	10	59
11	Spain	▼	10	58
12	Turkey	▲	17	58
13	Denmark	▲	29	56
14	Israel	▼	7	55
14	Greece	▼	13	55
14	Malta	▲	17	55
17	Slovenia	▼	8	54
18	Italy	▼	15	52
18	Russian Federation	▲	29	52
18	Lithuania	▲	29	52
21	Czechia	▲	23	49
21	Estonia	▲	23	49
21	Poland	▲	23	49
21	Sweden	▼	15	49
21	Croatia	▼	17	49
26	Latvia	▼	23	48
26	Austria	▼	20	48
28	Cyprus	▼	27	47
28	Luxembourg	▲	34	47
30	Portugal	▼	20	46
30	Slovakia	▲	32	46
30	Ukraine	▼	20	46
33	Bulgaria	▼	27	44
33	Germany	▲	36	43
36	Serbia	▼	33	38
36	Switzerland	▼	35	35
37	Bosnia & Herzegovina		(new)	25

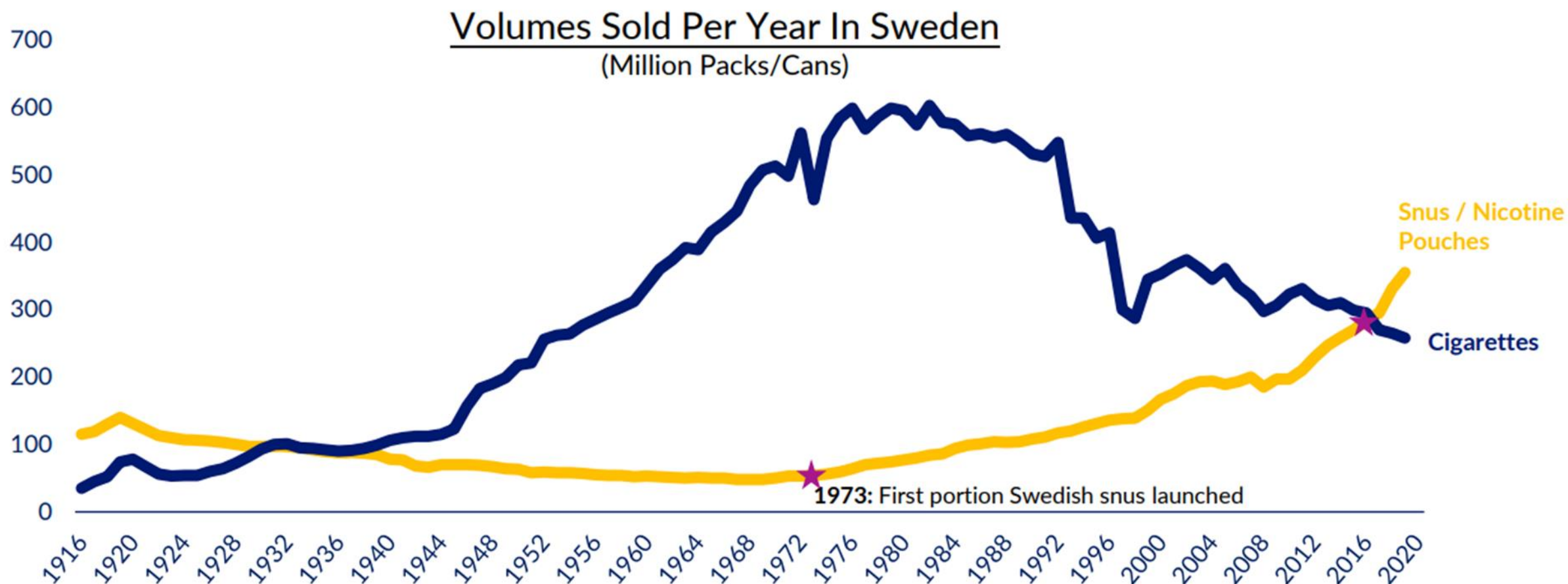


Joossens L, Olefir L, Feliu A, Fernandez E. The Tobacco Control Scale 2021 in Europe. Brussels: Smoke Free Partnership, Catalan Institute of Oncology; 2022. Available at: www.tobaccocontrolscalescale.org/TCS2021

TOBACCO CONTROL SCALE 2021



Significant Decline of Cigarette Sales in Sweden



Note: Temporal associations do not demonstrate cause and effect and are subject to inherent limitations. Specific factors associated with changing cigarette sales volumes over time have not been fully analyzed. 20 cigarettes per pack; 21 estimated average pouches in can for snus and nicotine pouches

Source: Swedish Match Estimates, SMD Logistics; [2019 TPSAC Meeting Materials and Information](#) | FDA. Investor Day 2023, presented September 28, 2023



TOBACCO USE IS AN IDEAL AREA FOR HARM REDUCTION

Tobacco products are used largely because of nicotine.

Pure nicotine, and even unburned tobacco, is not the primary cause of tobacco-related morbidity and mortality.

Most negative health effects are caused when tobacco is burned.

Statement from FDA Commissioner Scott Gottlieb March 15 2018 on Harm Reduction

“nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources”.

Statement from FDA Commissioners Scott Gottlieb and Mark McLellan April 2024

“ For these currently nicotine-addicted adult smokers, the opportunity to convert to noncombustible products offering nicotine delivery without the combustion-related health risks should be a renewed part of the public health agenda”.

JAMA April 11, 2024

THE ROLE OF NICOTINE

What Makes Tobacco Use Harmful?

Nicotine is what keeps people using tobacco products. **However, it's the thousands of chemicals contained in tobacco and tobacco smoke that make tobacco use so deadly.** Some of these chemicals, known to cause lung damage, are also found in some e-cigarette aerosols.

This toxic mix of chemicals—**not nicotine**—cause the [serious health effects among those who use tobacco products](#), including fatal lung diseases, like chronic obstructive pulmonary disease (COPD) and cancer.

FDA's Proposed Rule on Reduced Nicotine Levels Jan 15 2025

DEATH RATES (PER 100,000) ATTRIBUTABLE TO TOBACCO, WHO 2012

	Sweden		European Union Member States other than Sweden	
Men (age 60-69)	Median	Min	Median	Max
Lung cancer	87	91	220	399
Other cancer	36	41	105	217
All cardiovascular	72	107	170	618
All causes	222	378	550	1388

THE GLOBAL BURDEN OF DISEASE STUDY, WHO 2017

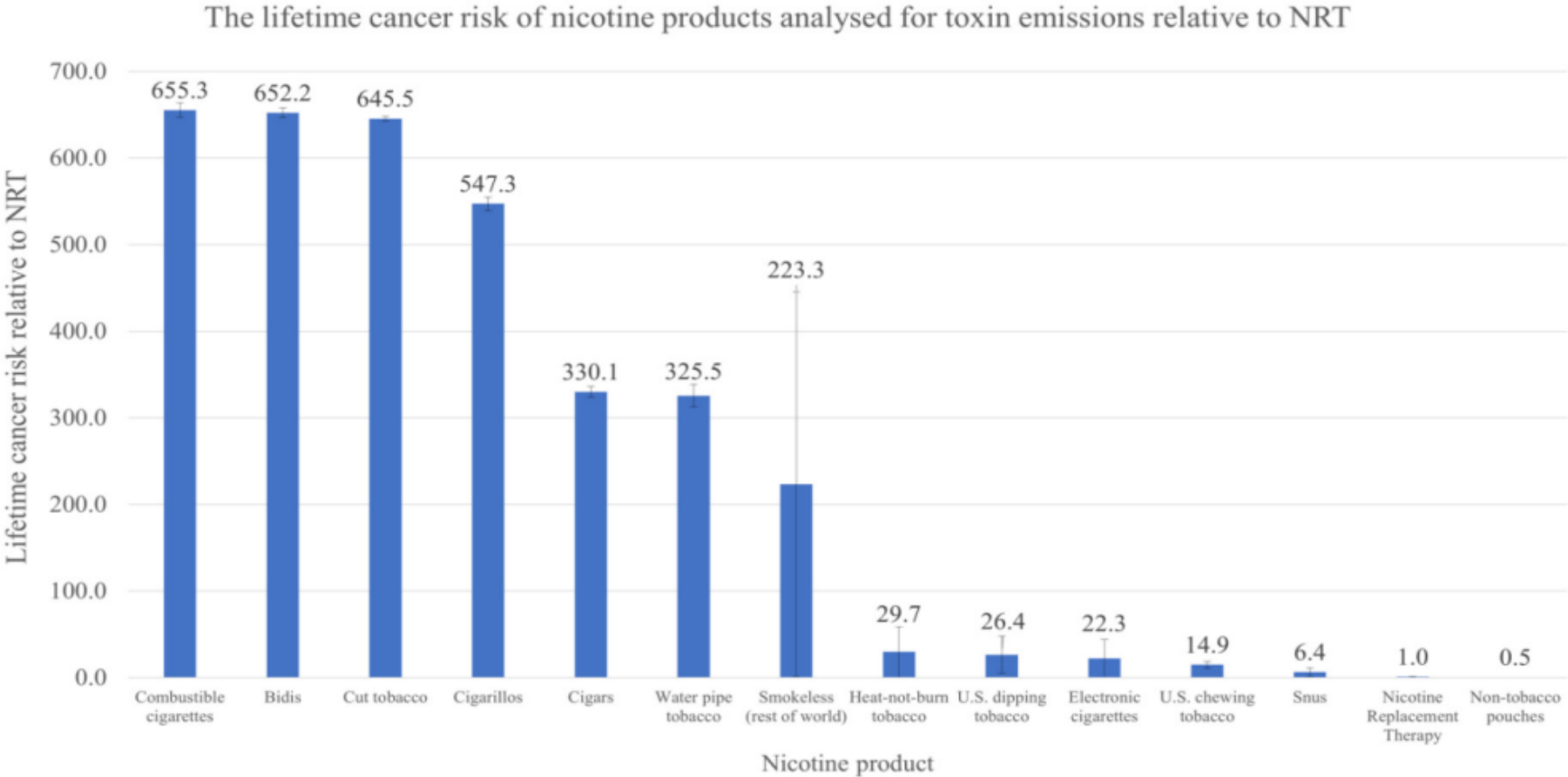
	Sweden		European Union Member States other than Sweden	
Total all cases	Median	Lowest	Weighted mean	Highest
Men total population	70	76	125	252
Men age 50-54	38	61	130	412
Women total population	52	19	44	79

SWEDISH SNUS WAS RECOGNIZED AS A LESS HARMFUL TOBACCO PRODUCT BY THE US FOOD AND DRUG ADMINISTRATION

“The available scientific evidence, including long-term epidemiological studies, shows that relative to cigarette smoking, exclusive use of these specific smokeless tobacco products poses lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis”

<https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products>

Relative risk hierarchy for cancer based on “emissions” of HPHCs



Source: Murkett R, Rugh M and Ding B. Nicotine products relative risk assessment: an updated systematic review and meta-analysis [version 2]. F1000Research 2022, 9:1225 (doi: 10.12688/f1000research.26762.2)

In German men the tobacco attributable death rate is 80.000/year.

If the death rate had been the same as among Swedish men the yearly death rate from tobacco use would have been 36.000.

Thus 44.000 deaths could have been delayed.

Percent daily use of tobacco and nicotine products

	Total	Women	Men
Smoking	4,9	5,1	4,7
Snus + pouch use	17,8	11,5	23,8
Any tobacco	16,7	9,8	23,2
Any nicotine	22,5	16,7	28,0
Dual use	0,6	0,5	0,8

Swedish Inventions

Non-tobacco
nicotine pouches.



Nicotine replacement



Snus



Nicotine pouches. The most recent harm reduction product.



In 2008, Nicotnovum registered the first non-tobacco nicotine pouch Zonnic as a medicinal NRT

These products are generally sold as consumer products and have similar ingredients, except flavourings and sometimes higher nicotine, as NRT but are so far unregulated and needs regulation.

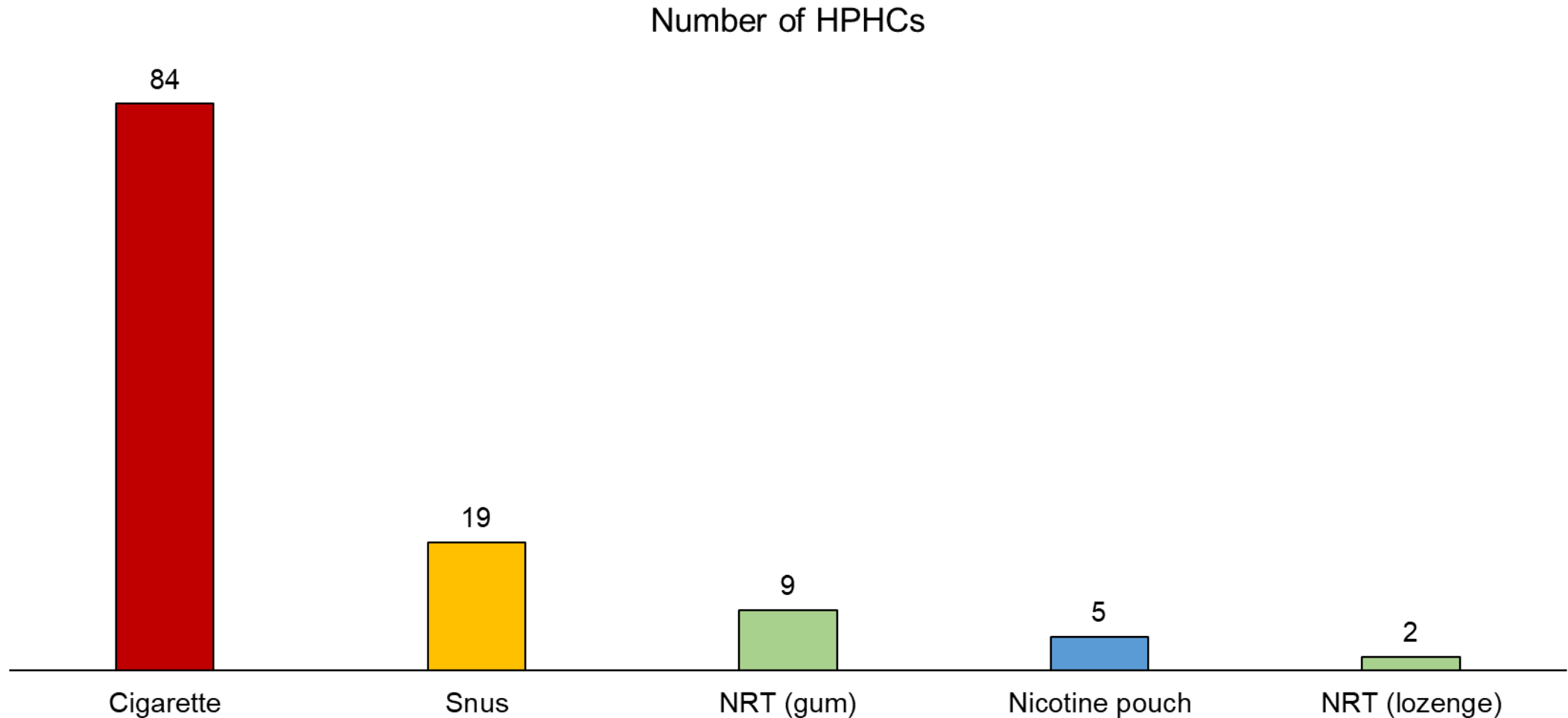


THE CONTENT OF A NICOTINE POUCH IS VERY SIMILAR TO NRT

ZYN (nicotine pouch)	Nicorette gum (NRT)	ZONNIC pouch (NRT)
Pharma grade nicotine	Pharma grade nicotine	Pharma grade nicotine
Microcrystalline cellulose Hydroxypropyl cellulose	Gum base Glycerine	Microcrystalline cellulose
Acesulfame potassium E950 Maltitol	Acesulfame potassium E950	Acesulfame potassium E950 Aspartame E951
Sodium carbonate Sodium bicarbonate	Sodium carbonate Sodium bicarbonate	Trisdium phosphate Ascorbyl palmitate
Flavorings	Flavorings	Flavorings

The health and adverse effects would be very similar to NRTs.

THE NUMBER OF HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS (HPHC) IN A NICOTINE POUCH IS SIMILAR TO NRT



What is the absolute and relative safety of the actual product itself?

Harmful and potentially harmful constituents

Red = NRT > Pouch

Blue = Pouch > NRT

Analytes	Unit	Average for nicotine gum 4mg and lozenge 4mg (Nicorette)	Average for 4 different nicotine pouches (Lyft)
Formaldehyde	µg/g	<1.0	<1.0
Acetaldehyde	µg/g	<1.0	<1.0
Acrolein	µg/g	<0.05	<0.05
Crotonaldehyde	µg/g	<0.05	<0.05
NAB	ng/g	<10	<10
NAT	ng/g	<10	<10
NNN	ng/g	<10	<10
NNK	ng/g	<10	<10
NDMA	ng/g	<0.2	<0.2
Benzo(a)pyrene	ng/g	<1.0	<1.0
1,3 Butadiene	ng/g	<20	<20
Benzene	ng/g	<5.0	<5.0
Cadmium	ng/g	<20	<10
Chromium	ng/g	397	113
Mercury	ng/g	<20	<20
Nickel	ng/g	151	<50
Arsenic	ng/g	<50	<50
Lead	ng/g	37	<20
Nitrate	µg	<1.0	<1.0
Aflatoxin B1	ng/g	<1.0	<1.0
Aflatoxin B2	ng/g	<0.5	<1.0
Aflatoxin G1	ng/g	<0.5	<1.0
Aflatoxin G2	ng/g	<0.5	<1.0
Ochratoxin A	ng/g	<0.5	<0.5

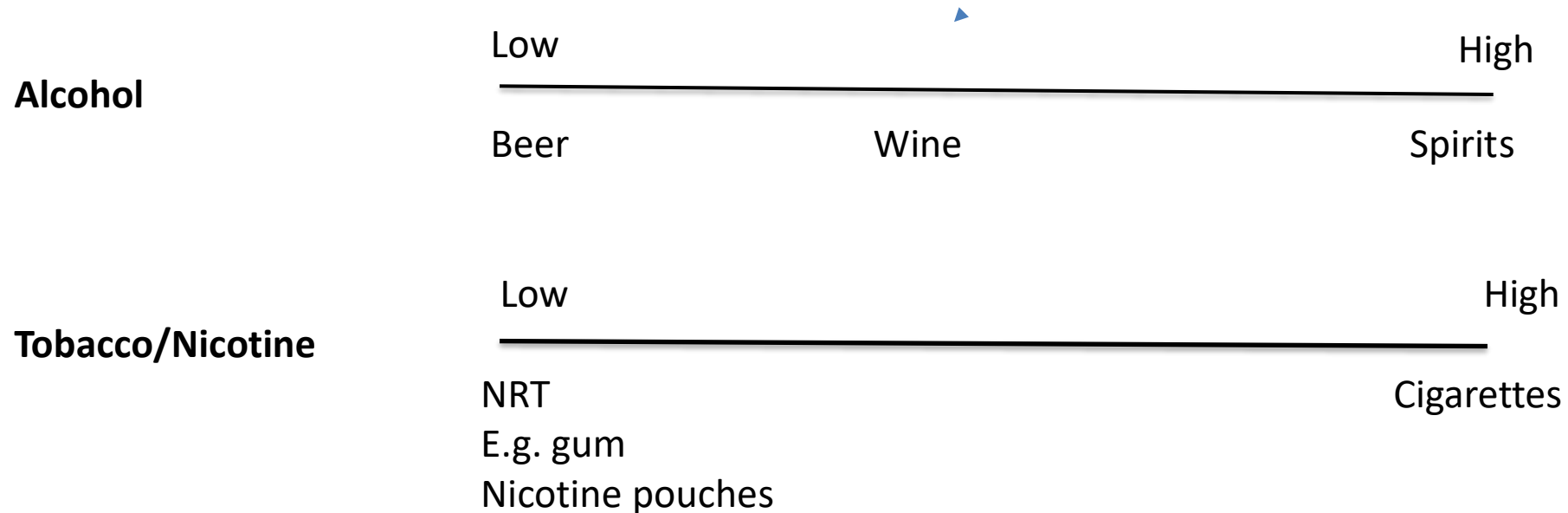
Tobacco free nicotine pouches are likely to have the best potential for harm reduction among

- a) smokers who switch and
- b) naive subjects who otherwise would have started with other nicotine and tobacco containing products.

THE SWEDISH GOVERNMENT ACTIONS

- Secretary of Health endorsing a harm reduction perspective for nicotine products
- Lowered tax on snus – 20% and increased tax on cigarettes +10% November 1 2024.
Price in Euro a cigarette 31 cent, a snus bag 0,22 cent, a non-tobacco pouch 0,18 cent
- Sweden is at Endgame 4,9% smokers.

A REGULATORY SYSTEM FOR TOBACCO/NICOTINE PRODUCTS



Important features with the alcohol regulation:

Taxation and **Availability** according to harm and **Minimum Age** for purchase.

SAME SYSTEM CAN BE USED FOR TOBACCO/NICOTINE PRODUCTS

Conclusions

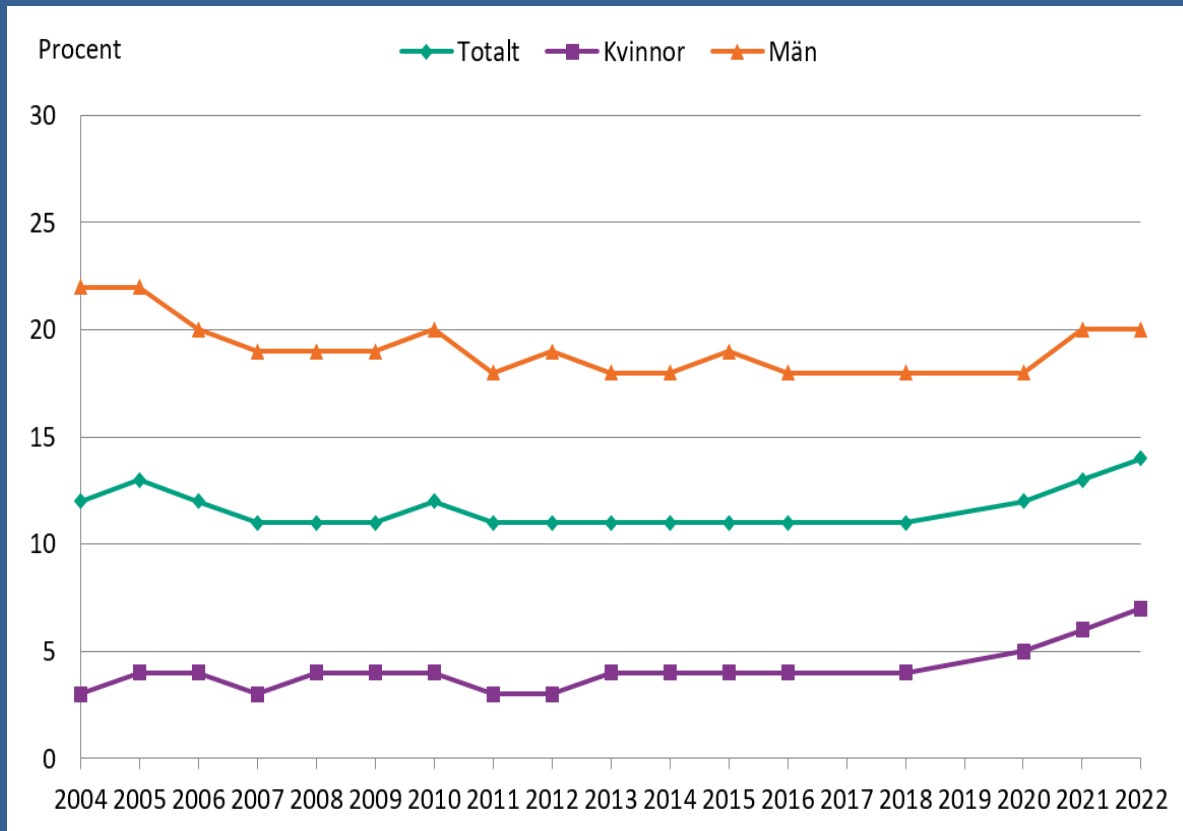
- Smoking prevalence can be reduced with alternative products
- For Sweden convincing data of reduced harm
- Can happen without resource demanding governmental policies

Obstacles for embracing harm minimisation.

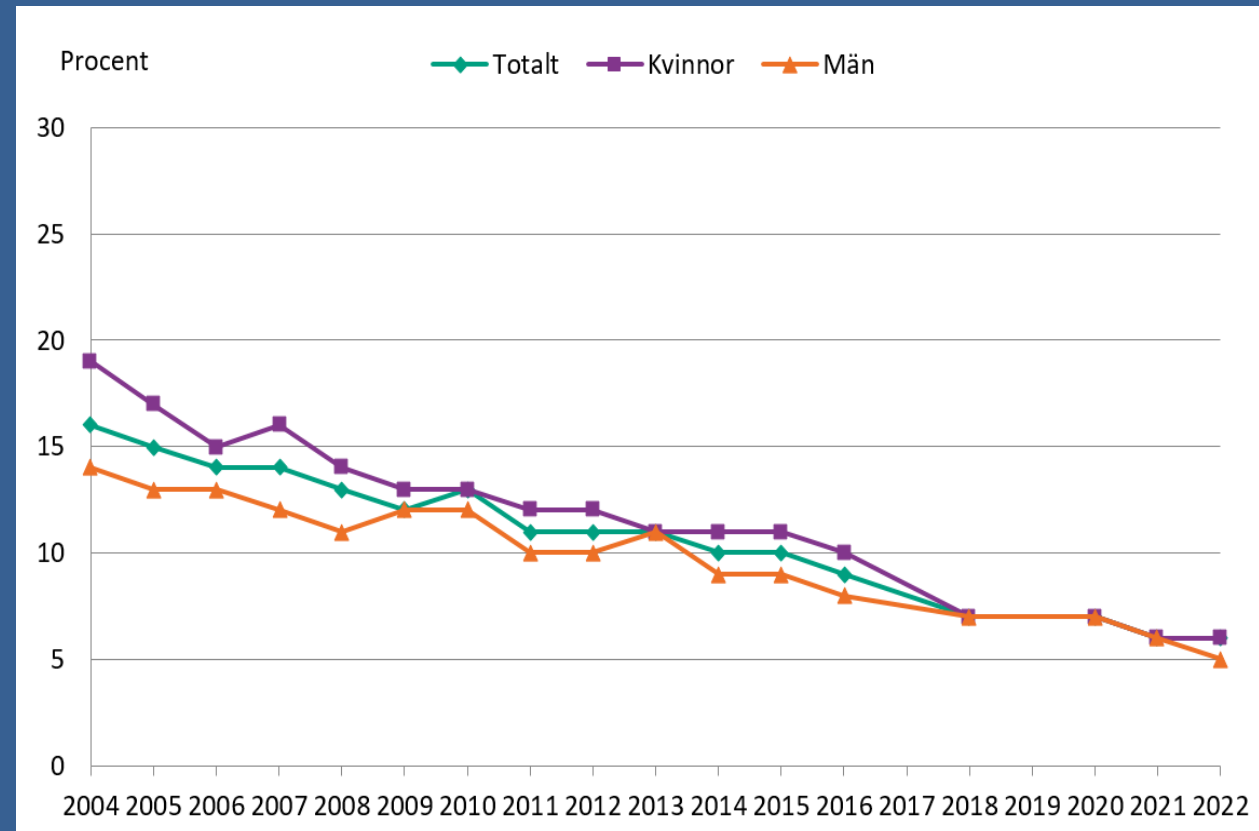
- Belief that nicotine is more harmful than it is.
- Endgame not for smoking but for nicotine
- There can be dependence to nicotine
- The old tobacco industry is profiting from reduced harm products.

Thank you for your attention.

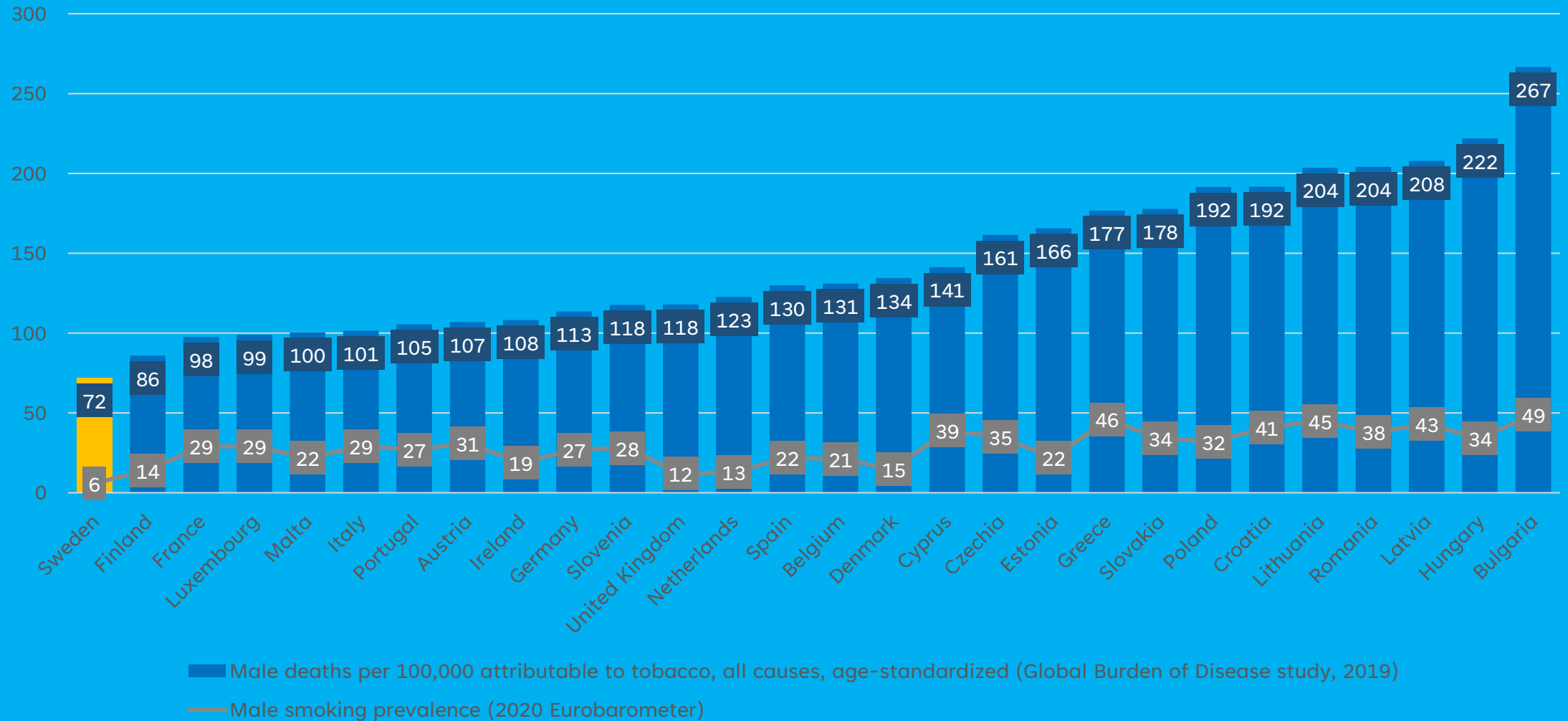
Daily snus use 16 – 84 years



Daily smoking 16 – 84 years

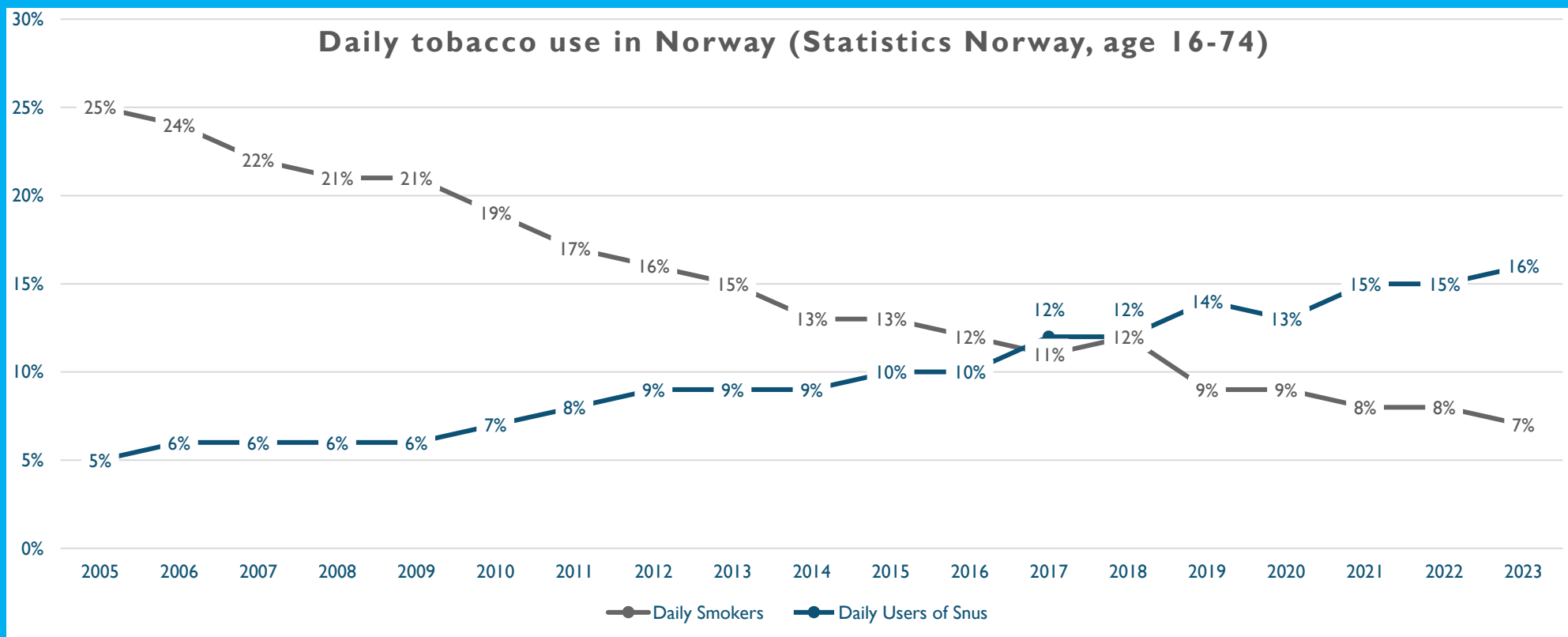


SWEDISH MALES HAVE THE LOWEST SMOKING PREVALENCE AND TOBACCO-ATTRIBUTABLE MORTALITY IN THE EUROPEAN UNION

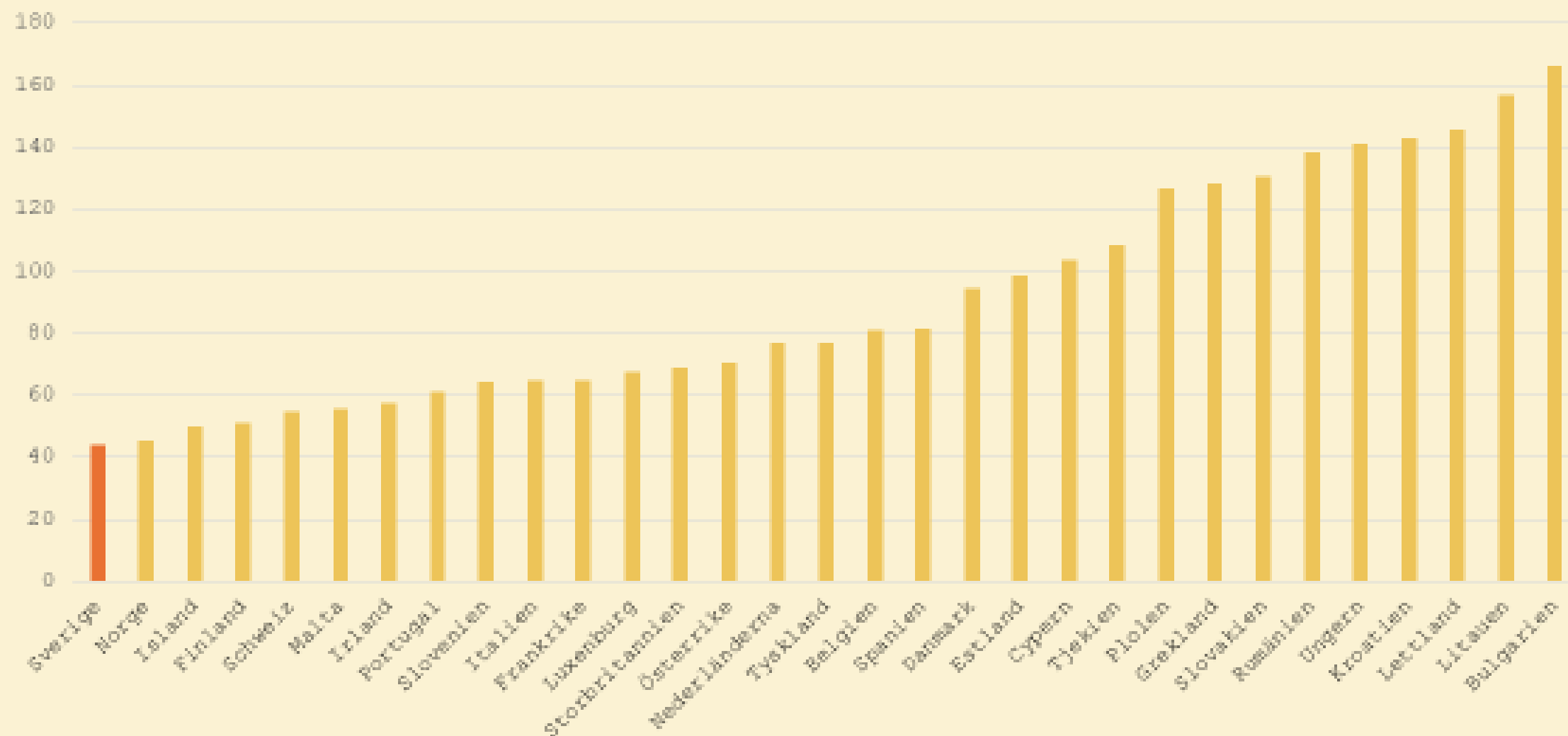


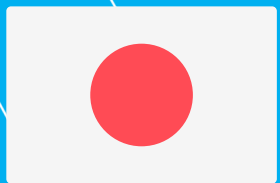


SMOKING DECLINE IN NORWAY SINCE 2005

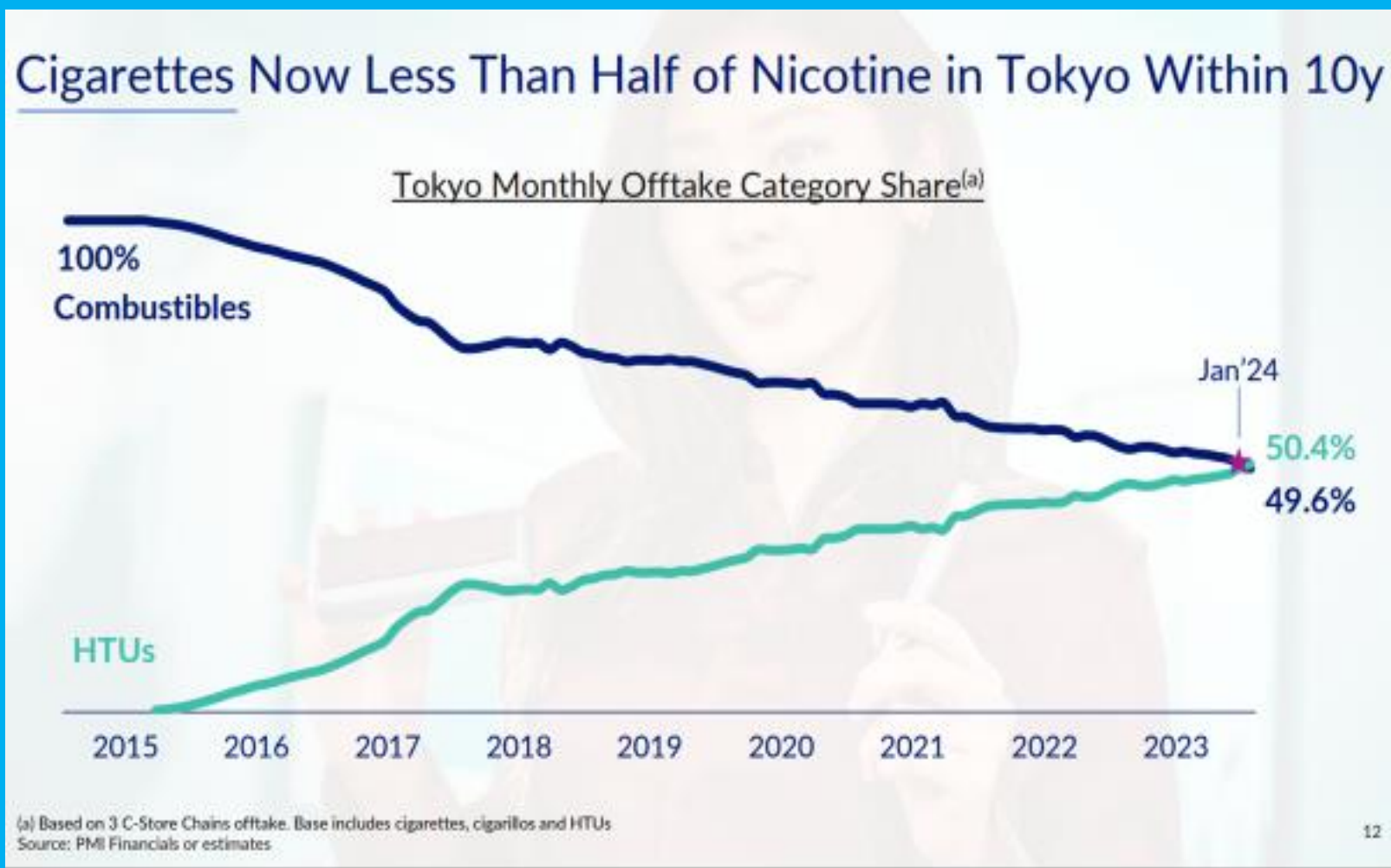


Tobacco attributable deaths-males per 100 000, age standardised, all causes GBD 2021





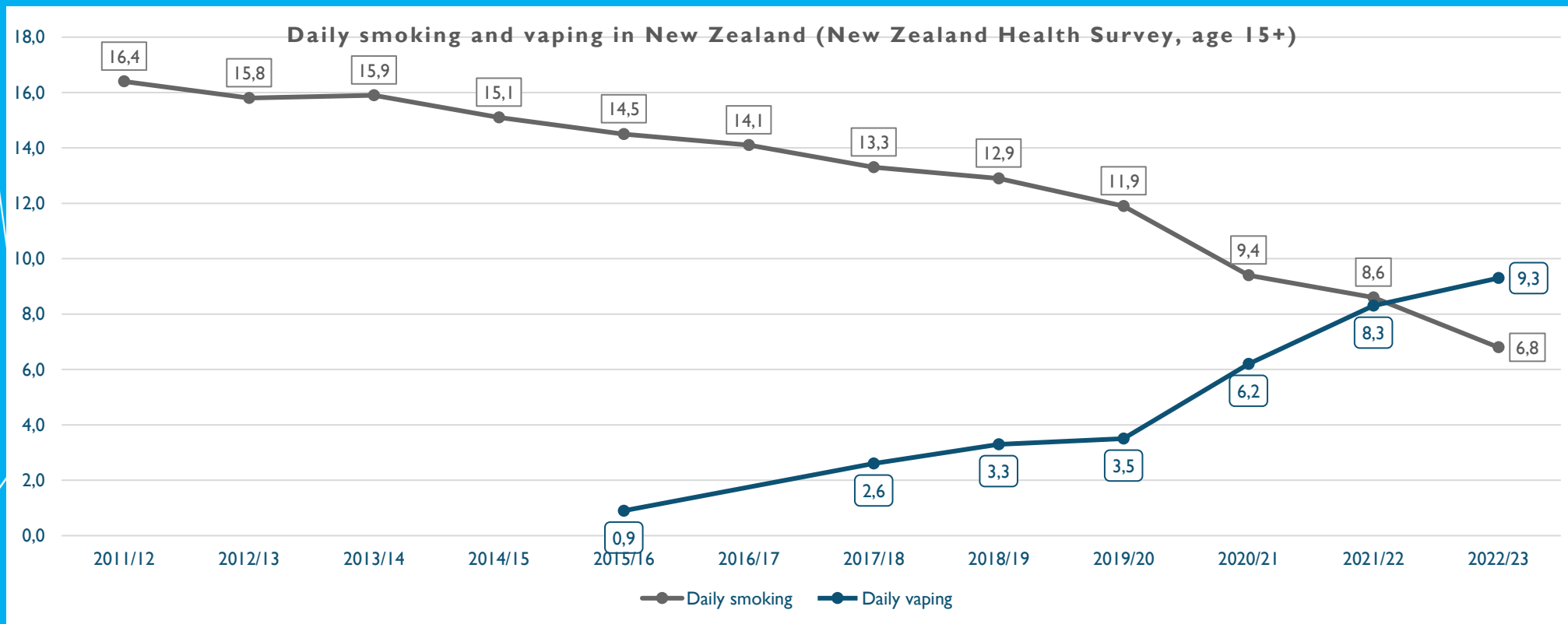
SIGNIFICANT DECLINE OF CIGARETTE SALES IN JAPAN





SMOKING DECLINE IN NEW ZEALAND

Prevalence of daily smoking in new Zealand (age 15+): rapid uptake of vaping coincided with rapid decrease in smoking



What is the absolute and relative safety of the actual product itself?

Harmful and potentially harmful constituents

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Ochratoxin A	ng/g	<0.5	<0.5

Figure 4. The relative risk hierarchy of the 15 categories of nicotine products.

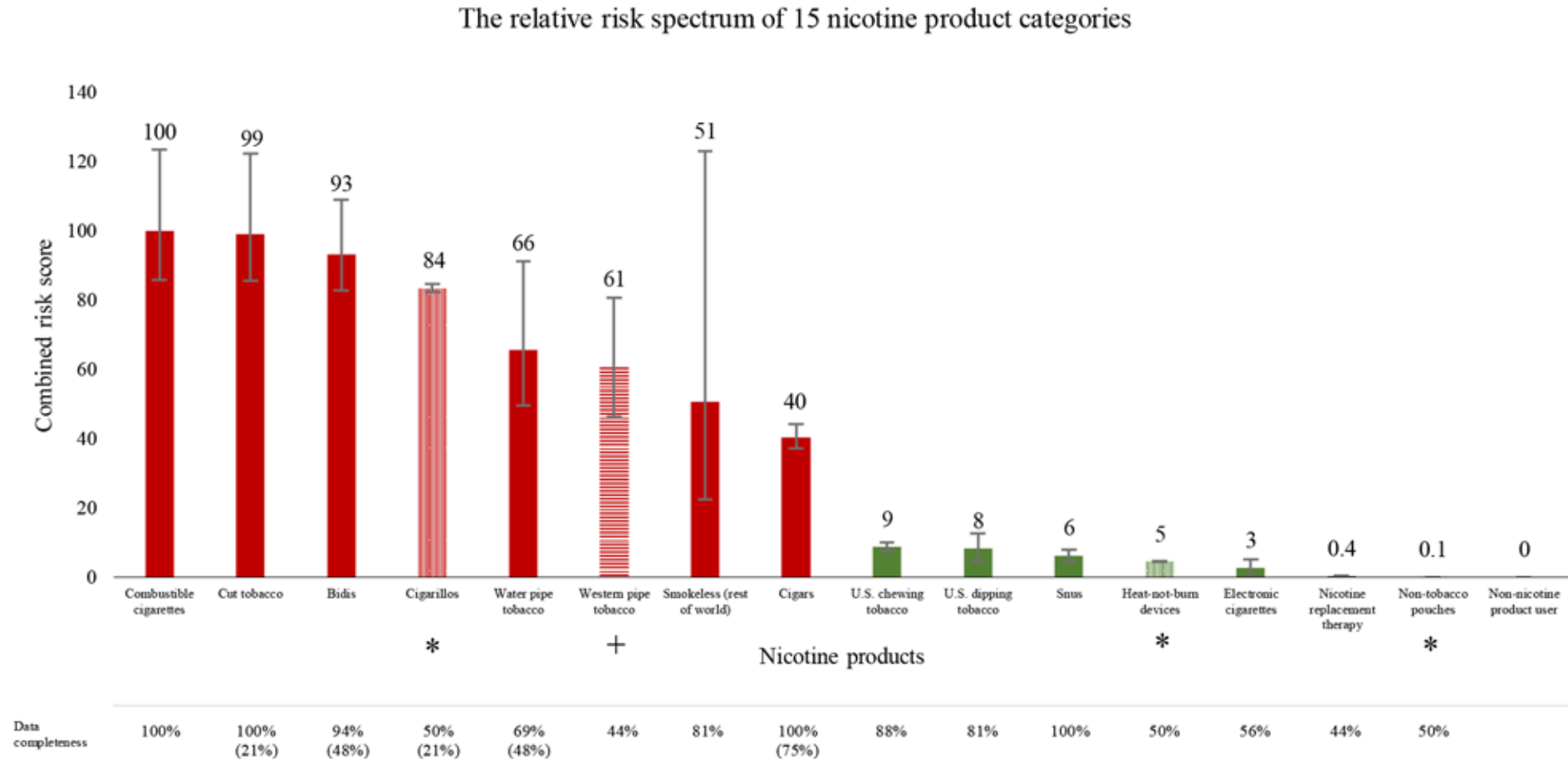
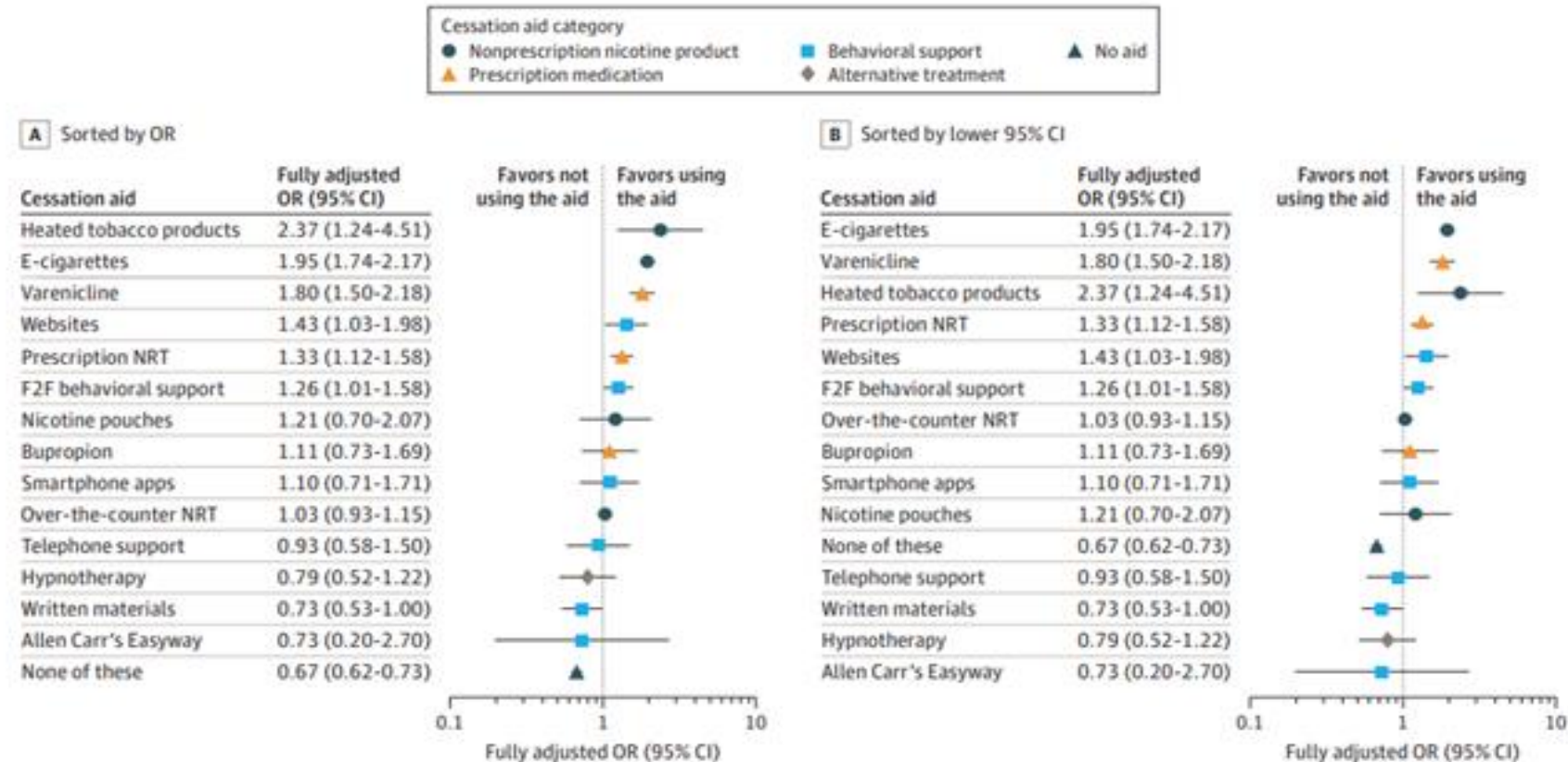


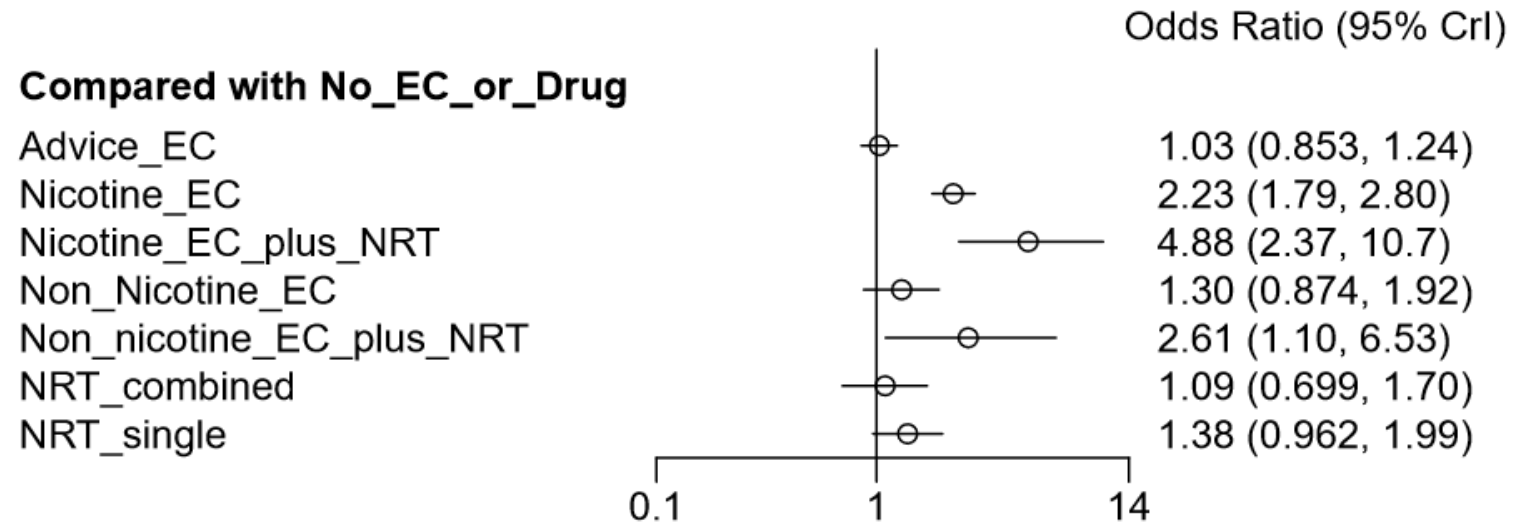
Figure 2. Fully Adjusted Associations Between Use of Cessation Aids and Quit Success



Data shown are the results of fully adjusted logistic regression models testing the association between use of a given aid and success in quitting smoking. Results for each individual aid are adjusted for use of all other cessation aids plus covariates (model 3).

Results for unaided quitting (ie, none of these) are adjusted for covariates (model 2). Error bars represent 95% CIs. F2F indicates face-to-face; NRT, nicotine replacement therapy; OR, odds ratio.

Smoking Cessation for Advice, NRT and E-cig



Cochrane database of systematic reviews, Lindson et al. 2025

Table 1. Prevalence of Use of Cessation Aids in England, Across the Whole Study Period and in 2023-2024^a

Cessation aid used in most recent quit attempt ^b	Whole study period (N = 25 094)		2023-2024, % (95% CI) (n = 1642) ^d
	No. ^c	% (95% CI)	
E-cigarettes ^e	4459	19.0 (18.4-19.5)	40.2 (37.6-42.8)
Over-the-counter NRT	6258	24.5 (23.9-25.1)	17.3 (15.3-19.2)
Websites ^e	430	1.9 (1.7-2.0)	4.6 (3.5-5.7)
Prescription NRT	1842	7.0 (6.6-7.3)	4.5 (3.4-5.5)
Smartphone apps ^e	186	0.8 (0.7-0.9)	3.6 (2.6-4.7)
Nicotine pouches ^e	84	0.4 (0.3-0.5)	3.1 (2.2-4.1)
Written self-help materials ^e	425	1.8 (1.6-2.0)	2.3 (1.5-3.0)
Face-to-face behavioral support	1013	3.8 (3.6-4.1)	2.2 (1.5-2.9)
Telephone support	224	0.9 (0.8-1.0)	1.3 (0.8-1.9)
Hypnotherapy	213	0.9 (0.7-1.0)	1.2 (0.7-1.8)
Varenicline	1208	4.8 (4.5-5.1)	1.1 (0.5-1.7)
Bupropion	346	1.3 (1.2-1.5)	0.9 (0.4-1.5)
Heated tobacco products ^e	72	0.3 (0.2-0.3)	0.7 (0.3-1.1)
Allen Carr's Easyway ^e	45	0.2 (0.1-0.3)	0.5 (0.1-0.9)
None of these	11 079	44.2 (43.5-44.9)	40.8 (38.2-43.4)

Abbreviations: e-cigarette, electronic cigarette; NRT, nicotine replacement therapy.

^a Corresponding data stratified by socioeconomic position are provided in eTable 2 in [Supplement 1](#).

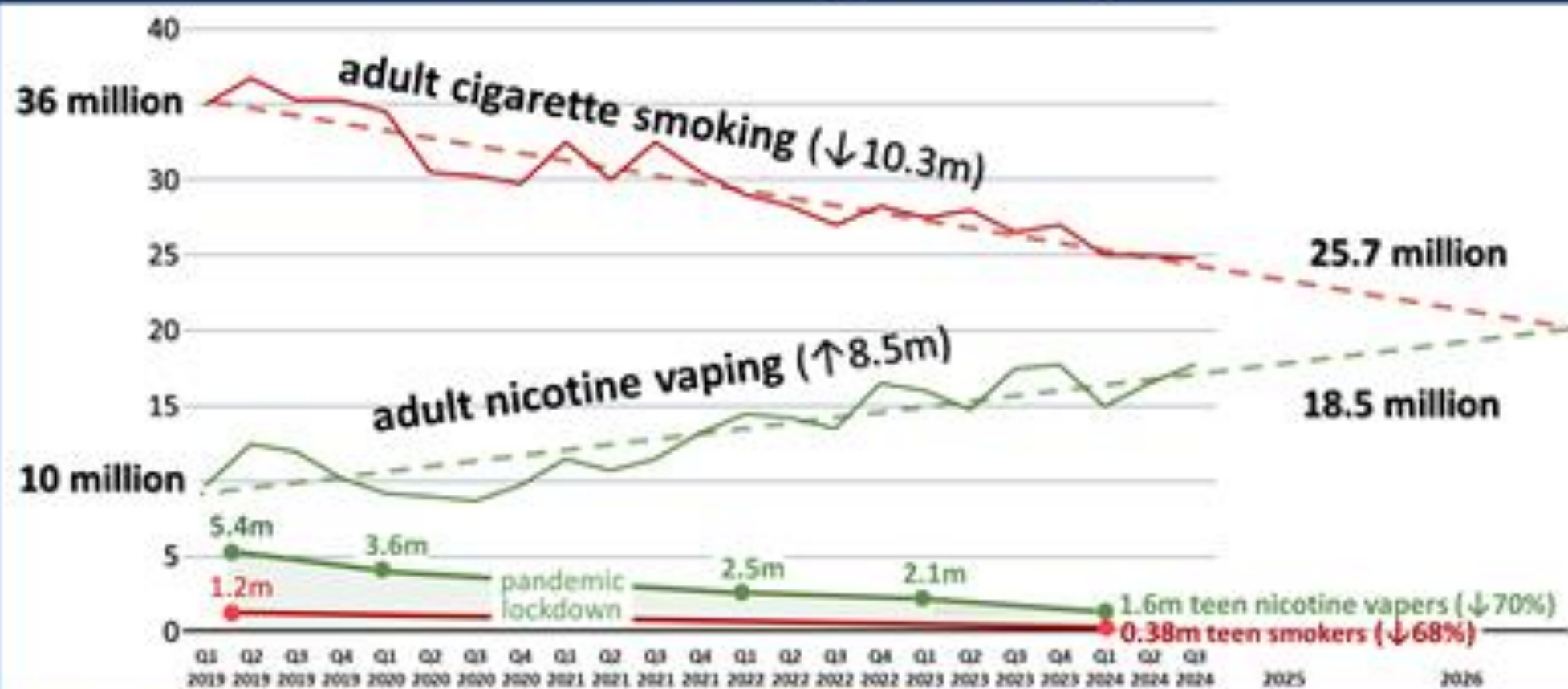
^b Not mutually exclusive; sorted from the most to least popular in 2023-2024.

^c Unweighted number of participants who reported using each aid.

^d Up-to-date estimates of prevalence of the use of each aid among participants surveyed between January 2023 and June 2024.

^e Use of written self-help materials was assessed from March 2007, websites and Allen Carr's Easyway from April 2008, e-cigarettes from July 2009, smartphone apps from February 2012, heated tobacco products from April 2016, and nicotine pouches from June 2021; use was imputed as 0 before this.

Four massive changes in five years



Adult data: CDC National Health Interview Survey
https://www.cdc.gov/NHISDataQueryTool/ER/Quarterly/index_quarterly.html
Teen data: CDC National Youth Tobacco Survey



"We do know that e-cigarettes - as a general class - have markedly less risk than a combustible cigarette."
- Dr. Brian King, Director, FDA Center for Tobacco Products

Adult smoking and vaping daily

