Tobacco Harm Reduction with snus, nicotine pouches

The Swedish Experience

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- 1979 2005 Department of Oncology, Karolinska University Hospital
- 2006 2017 Scientific Affairs Group, Swedish Match AB
- 2017 Independent consultant

Population-based, case-control study of risk factors for head-neck (incl. oral) cancer

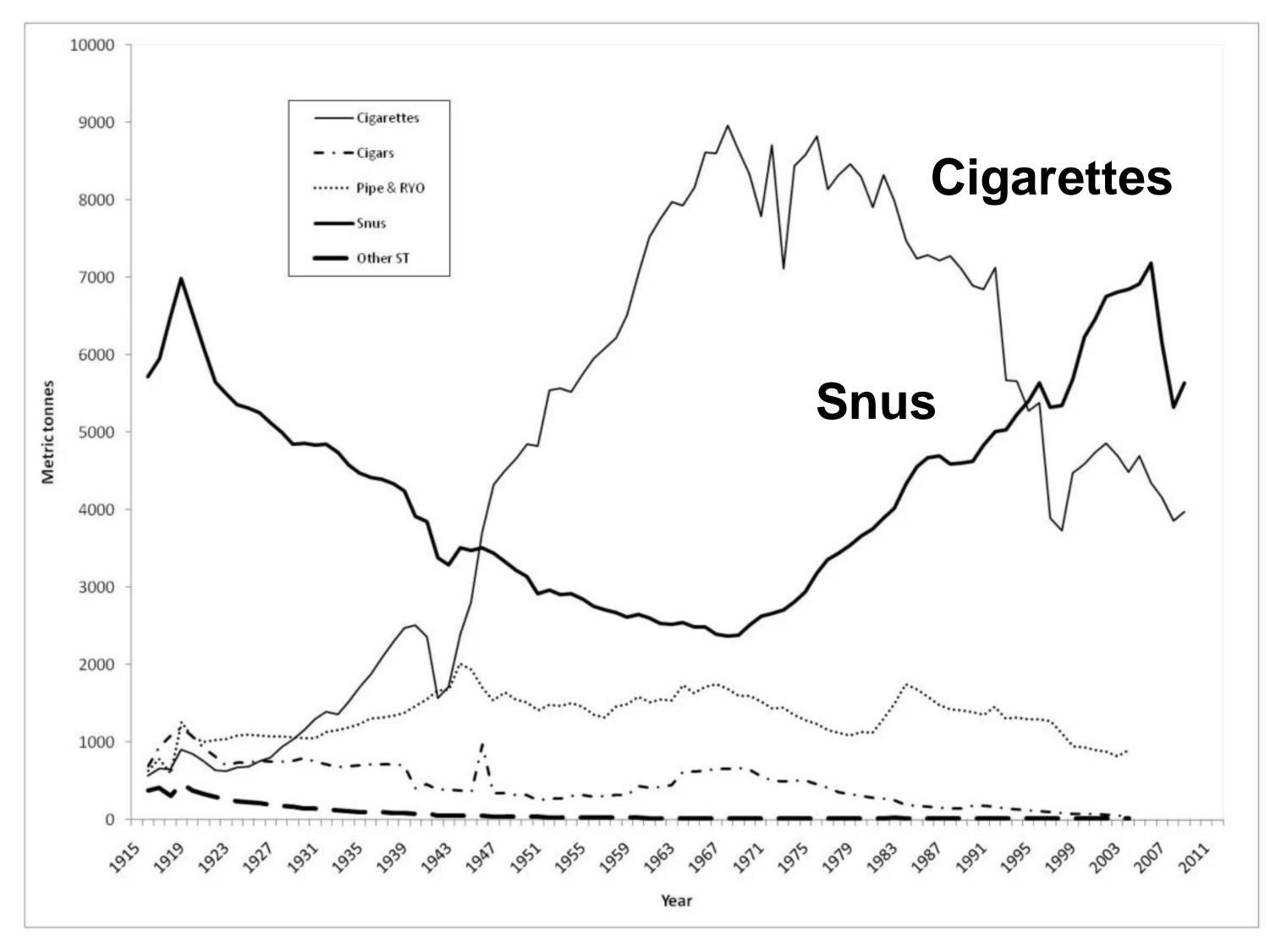
- Background
 - Smoking & alcohol major risk factors
- What about other exposures?
 - Diet
 - Work-related exposures
 - Swedish snus

Main findings, relative risks:

 Cigarette smoking 	6-7	
 Alcohol 	5	
 Smoking & alcohol 	10-15	
 Vitamin C 	0.8	
 Welding fumes 	1.2	
• Snus	1.0 (95% CI: 0.8-1.2)	

Lewin F, Norell SE, Johansson H, Gustavsson P, Wennerber J, Biörklund A, Rutqvist LE: Smoking tobacco, oral snuff, and alcohol in the etiologu of squamous cell carcinoma of the head and neck: a population-based case-referent study in Sweden.: Cancer 1998

Tobacco sales in Sweden in the 20th century according to product category



Ref: Rutqvist et al, 2011

Why did Swedish smokers start to switch to snus in the early 1970s

Drivers of the switch to snus?

- Reports of cancer risks associated with cigarette smoking (Royal College of Physicians, Surgeon General, etc)
- Snus deeply rooted in Swedish culture, generally viewed as being more "natural", not associated with "Big Tobacco"
- Student revolution, "Green movement" in the late 60s, 70s
- Pouched products (1972)
- Snus cheaper than cigaretters due to different excise taxes
- Can be used discreetly, not affecting others, unaffected by smoking bans, no 2nd hand smoke

Switch to snus was a "grass roots movement" among cigarette smokers, unrelated to either marketing by industry or regulatory actions by health authorities

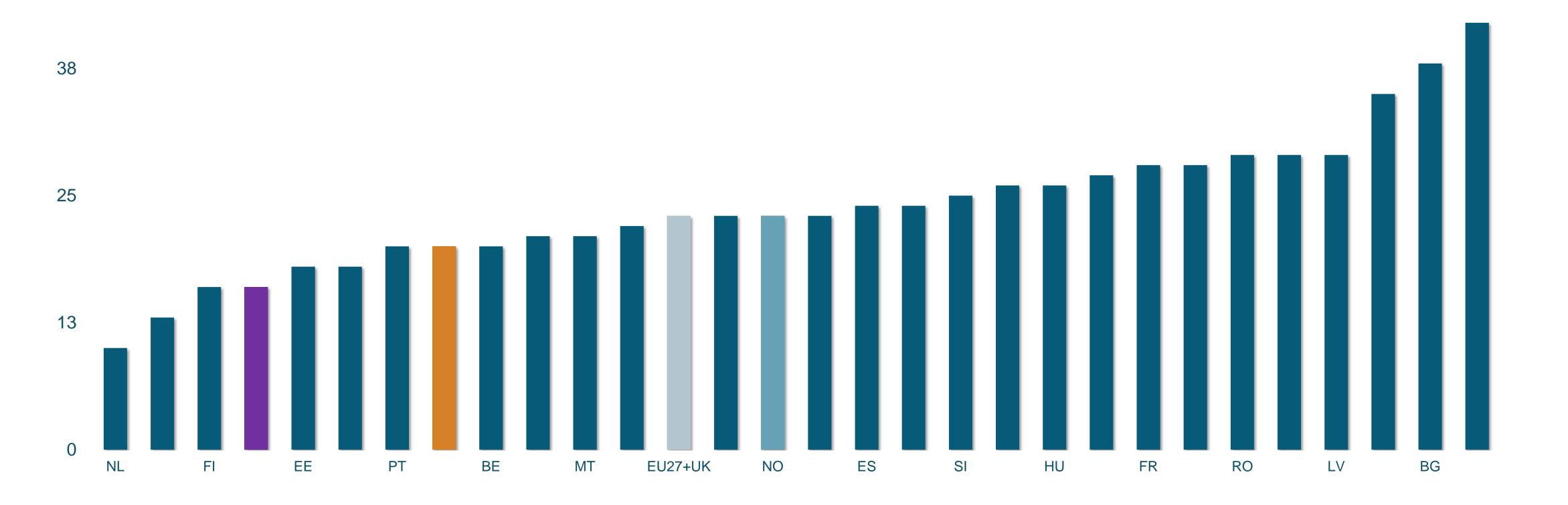
WHAT ABOUT GOVERNMENT ACTIONS, REGULATIONS, EUROPEAN UNION?

- 1. Swedish government, government agencies did not advocate snus as a smoking cessation aid (although in recent years accepting the vast risk differential between snus and cigarettes)
- 2. European Union: late 1990s TPD mandated a health warning on snus cans: "Causes cancer". This warning was dropped in 2001 (as it was contradicted by scientific studies), replaced by the generic warning ("May damage your health"), still no explicit acceptance of THR
- 3. During the past 10 years Swedish politicians have become more aware of the available science about snus and its health effects, general acceptance of the fact that snus is dramatically less risky than cigarettes, increased awareness of the concept of Tobacco Harm Reduction
- 4. Science-based regulation of both snus & nicotine pouches (still no rebgvulation of nicotine)
- 5. The current Swedish government coalition proposes a lowered excise tax on snus & nicotine pouches for 2024 (sic!)

Prevalence of daily tobacco use – cigarettes, e-cigarettes, heated tobacco products, water pipes oral, chewing or nasal tobacco – EU27+ UK + Norway (%)

Base: All respondents

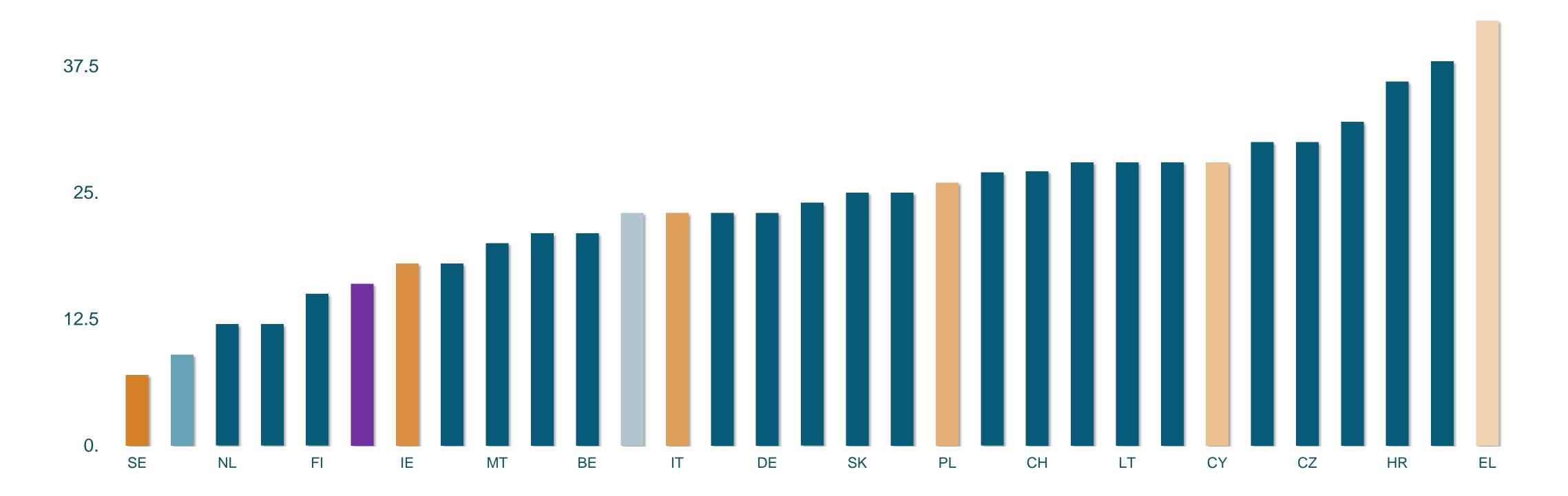
Value



Current tobacco smokers – EU27 + UK + Norway + Switzerland (%)

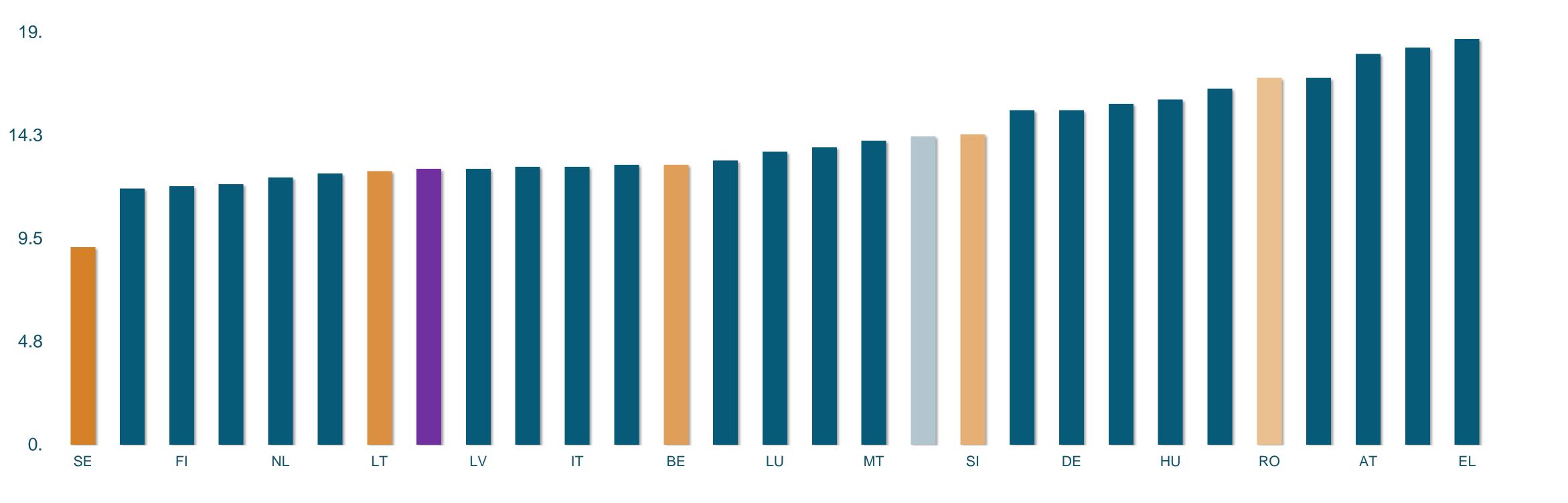
Base: All respondents

50. value



23.8

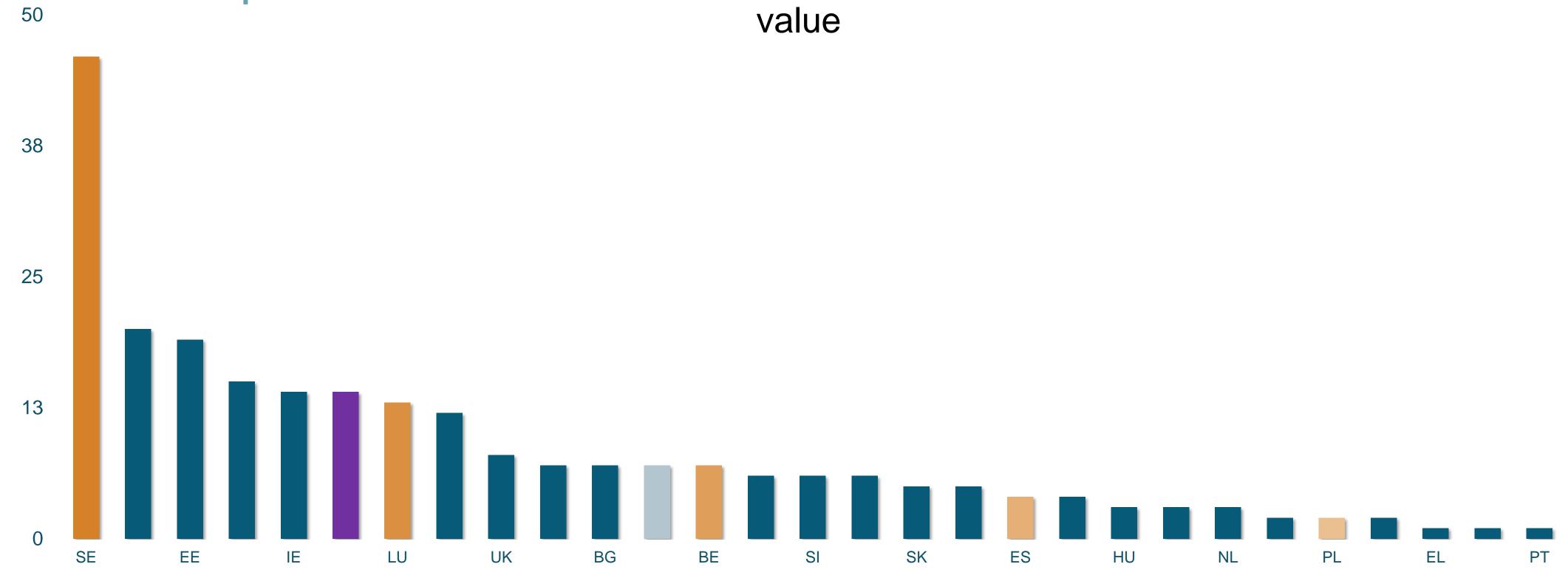
Average number of cigarettes smoked daily – EU27 + UK Base: Respondents who smoke cigarettes value



Used or tried oral tobacco (snus), chewing or nasal tobacco – EU27 + UK

(%)

Base: All respondents



WHO data on ratio of death rates* attributable to tobacco among males: Sweden vs other EU countries

Age (years)	All causes	Lung cancer	All CV
45-59	0.15**	0.24	0.13
60-69	0.27	0.38	0.19
70-79	0.42	0.49	0.33

* A ratio <1.0 indicates a lower death rate.

** The ratio shows that Swedish males only have 15% of the death ratein other EU countries

Ref: Ramström L, Wikmans T, Tobacco Induced Diseases, 2014

Adverse health effects of conventional cigarettes

Mechanisms, outcomes

- Cigarette smoke contains combustion products, some of which are highly carcinogenic
- Inhalation of cigarette smoke leads to a chronic irritation in the respiratory tract
- Unknown components in cigarette smoke contributes to a systemic, chronic inflammatory state in some habitual smokers (as evidenced by increases in blood markers such as fibrinogen & CRP)
- Excess mortality among cigarette smokers:
 - 1/3 due to 12-15 types of cancer (70% lung cancer)
 - 1/3 due to cardiovascular disease (myocardial infarction, stroke)
 - 1/3 due to COPD (e. g. chronic bronchitis, emphysema

It's not the nicotine that makes cigarette smoking a major health concern!

Swedish, epidemiological studies on long-term health outcomes among snus users published since the 1990s

- 200-300 publications
- >100,000 snus users
- Studies done by independent, university-based research groups
- Findings:
 - No increased risk of oral cancer
 - No increased risk of lung cancer
 - No increased risk of any other type of cancer
 - No increased risk of cardiovascular disease (myocardial infarction, stroke)

All tobacco products are not the same, some smokeless products (like Swedish snus, nicotine pouches) are clearly much less dangerous to health than conventional cigarettes

In 2019 FDA issued their first and hitherto only "modified risk order"for Swedish snus. The order authorises marketing of snus using health claims. The order was based on a review of all the scientific evidence about snus which shows reduced (or rather no) major health risks among users as well as a potential for public health benefit

"Using General snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis"

FDA, Center for Tobacco, Oct 22, 2019

But what about nicotine?

- Nicotine is a mild stimulant (like caffeine) that is unassociated with all of the major, smoking-related diseases
- Not completely safe for all users:
 - Adverse pregnancy outcomes among cigarettes smokers as well as snus users
 - No adverse effects among those who stop using nicotine after the 1st trimester
 - Potential adverse effect on the prognosis among patients diagnosed with cardiovascular disease ??

Nicotine

Problems, potential

- Addiction
- Adverse health effects in subsets of users?
- Positive effects on mood & cognition (like caffeine)
- Preventive effect in some neurological diseases (Parkinson's disease, Alzheimer's disease?)

Nicotine pouches: "Snus 2.0", the most promising future product for THR

- No tobacco
- No combustion/heating, no inhalation, no 2nd hand vapor/smoke
- "Controversial substances" (like carcinogenic nitrosamines) not an issue
- Similarities in usage & nicotine exposure permits using "snus epidemiology" as a proxy for potential adverse health effects ("worst case scenario")
- Functional advantages (no staining of teeth, halitosis, gum problems)
- Attractive also to new groups of smokers e g females
- Comparable nicotine delivery suggests comparable efficacy to help smokers quit cigarettes
- Consumer surveys in the US indicate that nicotine pouches are not attractive to current non-users of tobacco products

"THR with snus, nicotine pouches are solely developed, marketed by "Big Tobacco" to maintain and promote nicotine addiction..."

- THR with a non-combustible, low-risk tobacco product (nasal snuff) was first proposed by British tobacco researchers already in the 1970s
- THR prominent topic among the tobacco research community for more than 10-15 years
- Since 2017 the U.S. FDA explicitly aims to phase out conventional cigarettes with the help of novel, low-risk, nicotine delivery products
- THR with low-risk products (e-cigarettes) is promoted by Public Health England

Conclusions

- "Swedish Experience" clearly shows that THR with a low-risk, nicotine-delivery products, as an alternative to conventional cigarettes is a valid concept with potential positive public health effects
- "One size does not fit all"
 - Pharmaceutical nicotine delivery products
 - Snus
 - Nicotine pouches
 - E-cigarettes
 - "Heat not burn" products
- Need for science-based regulation of novel products (not arbitrary rules that act as "prohibition by stealth")
- Major factors working against THR
 - Ideology (instead of pragmatism)
 - Lack of knowledge about the scientific platform for THR
 - "Opinion-based" regulation rather than pragmatic regulation rooted in science