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Tobacco-Free Nicotine Pouches and their potential contribution to Tobacco Harm Reduction

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Conflict of interest statement

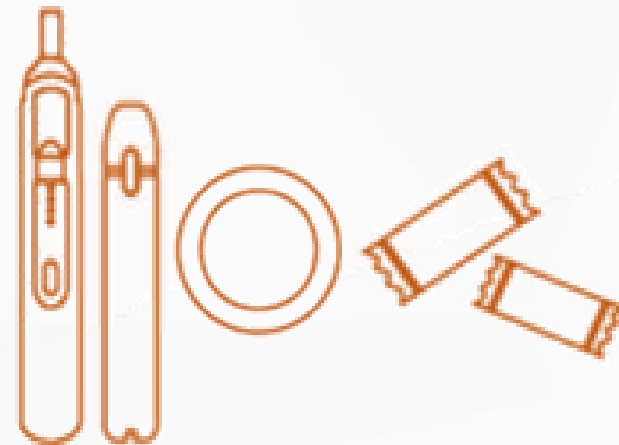
- I am an employee of Imperial Brands PLC
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What is tobacco harm reduction?

Tobacco harm reduction (THR) refers to strategies designed to reduce the health risks associated with tobacco smoking, but which may involve the continued use of nicotine/tobacco



**Next Generation Products (NGP)
deliver nicotine without burning tobacco**

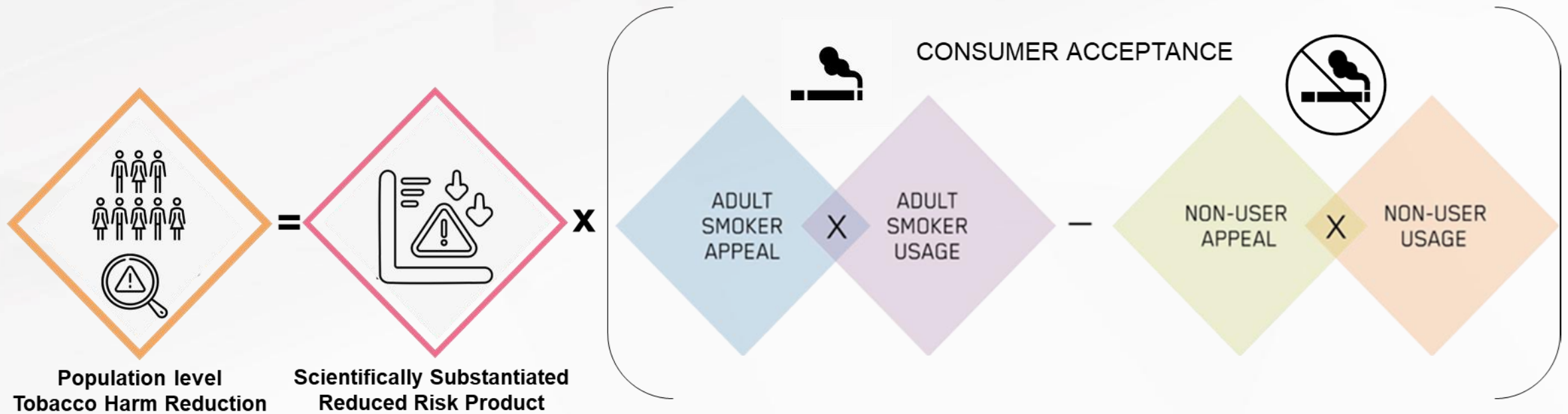


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NGP present an exciting Global Public Health opportunity

The THR equation is the framework that can reduce the demand and sale of combustible cigarettes - products that both meet the needs of consumers & are scientifically substantiated



Risks of smoking come from the combustion of tobacco, not nicotine

The way nicotine is delivered to the consumer plays a key role in determining the level of risk associated with using a particular product



Scientific evidence suggests that NGP may be potentially less harmful compared to cigarettes



Snus – an example of effective THR

Epidemiological data suggest that availability of snus in the Nordics led to low cancer rates and accelerated smoking cessation

Smokeless, it is consumed orally by placing under the lip



> 95-99%
less harmful than
cigarettes²



Gentle heating during manufacture reduces the number of cancer-causing chemicals in the tobacco¹



5% smoking
rates in Sweden
which is the lowest in
Europe³



UK Royal College
of Physicians⁴

*"In Norway, snus is
associated with
smoking cessation"*



Swedish males
have the lowest
incidence of lung
cancer in Europe⁵

23.3 vs 52.2
per 100,000 people

¹ New Nicotine Alliance UK. <https://nnalliance.org/snus-facts>;

² Gartner et al., 2010. Available at: [https://linkinghub.elsevier.com/retrieve/pii/S0140-6736\(07\)60677-1](https://linkinghub.elsevier.com/retrieve/pii/S0140-6736(07)60677-1);

³ Eurobarometer data 2017. Available at: <http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146>;

⁴ Royal College of Physicians, 2016. Available at: <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>;

⁵ Ferlay et al., 2013. Available at: <https://pubmed.ncbi.nlm.nih.gov/23485231/>



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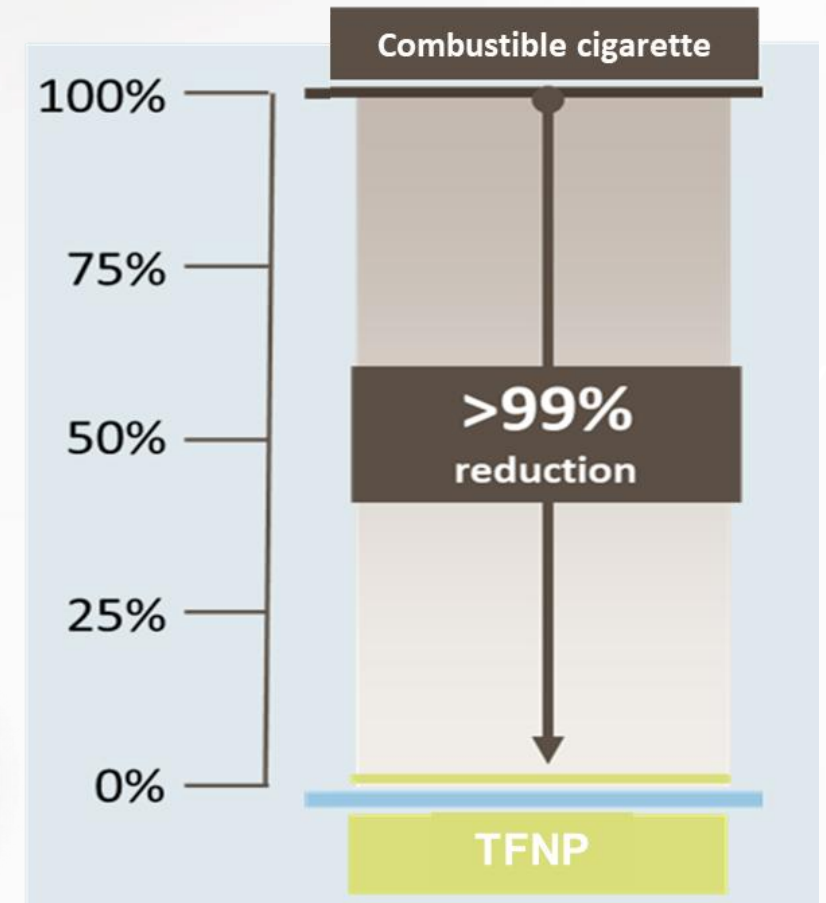
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TFNP contain nicotine but, unlike snus, do not contain tobacco and therefore offer even greater THR potential

PHARMACEUTICAL-GRADE
HIGH PURITY NICOTINE

PLANT FIBRE-BASED
SUBSTRATE OR DRY POWDER

FLAVOURINGS, HUMECTANTS
AND ADDITIVES

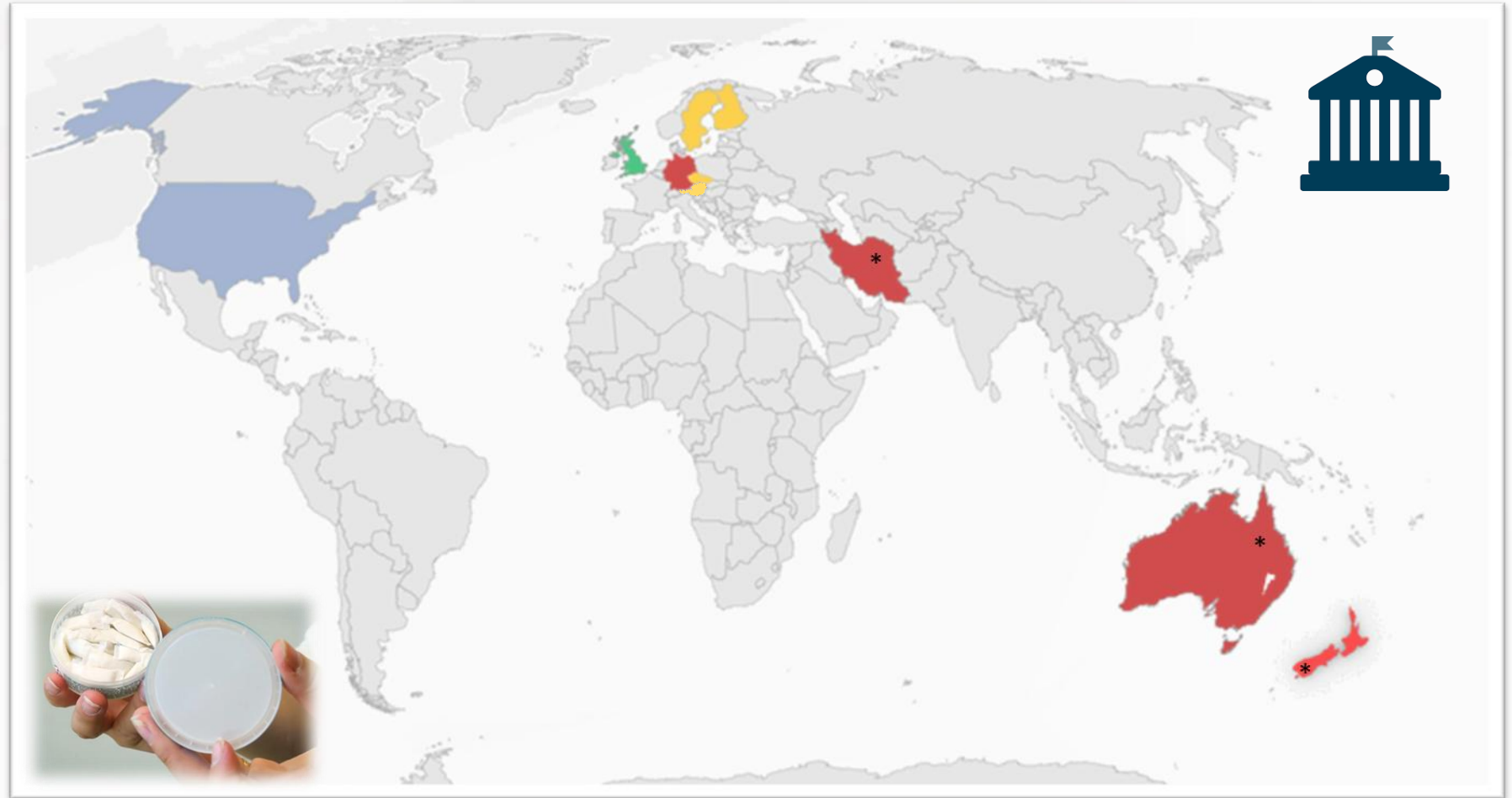


Laboratory tests indicated greater than 99% reduction in harmful chemicals in our TFNP compared to cigarettes

TFNP can play a meaningful role in THR

However, a successful THR approach requires proportionate regulation

- ▶ Many regulators are cautious about the introduction of TFNP due to lack of long-term data on their potential health effects
- ▶ Regulations differ markedly around the world.



Example of different TFNP regulations around the world.

GREEN: under CLP regulation. **RED:** currently banned or treated as illegal products; **YELLOW:** introduced specific restriction; **BLUE:** PMTA required. **RED*:** TFNP are banned unless they are approved as medicines



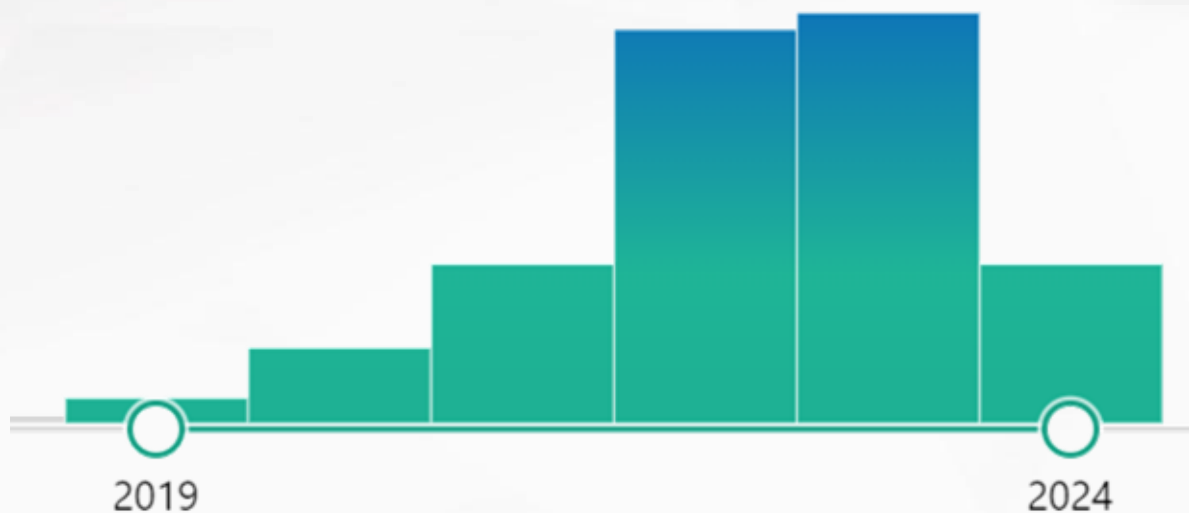
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IMB conducted a review on the potential role of TFNP in THR

The findings of this review may help inform evidence-based regulation

- ❖ Relatively new product category
- ❖ Perceived lack of understanding of their potential contribution to THR
- ❖ Growing scientific research since 2019

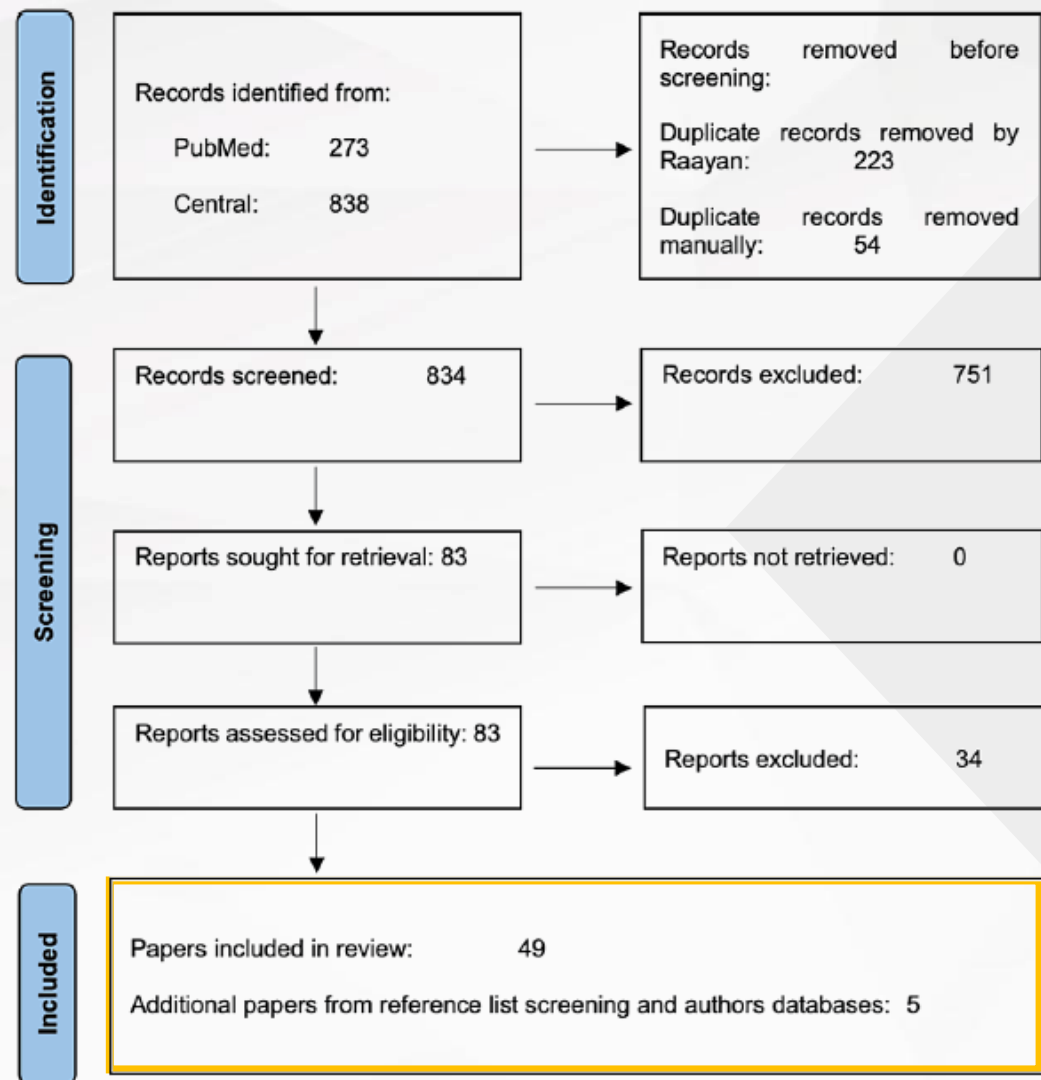


Bar chart generated by searching for “*Tobacco-Free Nicotine Pouches*” through PubMed



A total of 54 studies reviewed

Databases searched from inception to May 31, 2023



Chemical and Toxicological Analysis

11

Clinical studies & subjective effects

8

Biomarkers and Disease

6

Prevalence and Motivation

25

Others

4

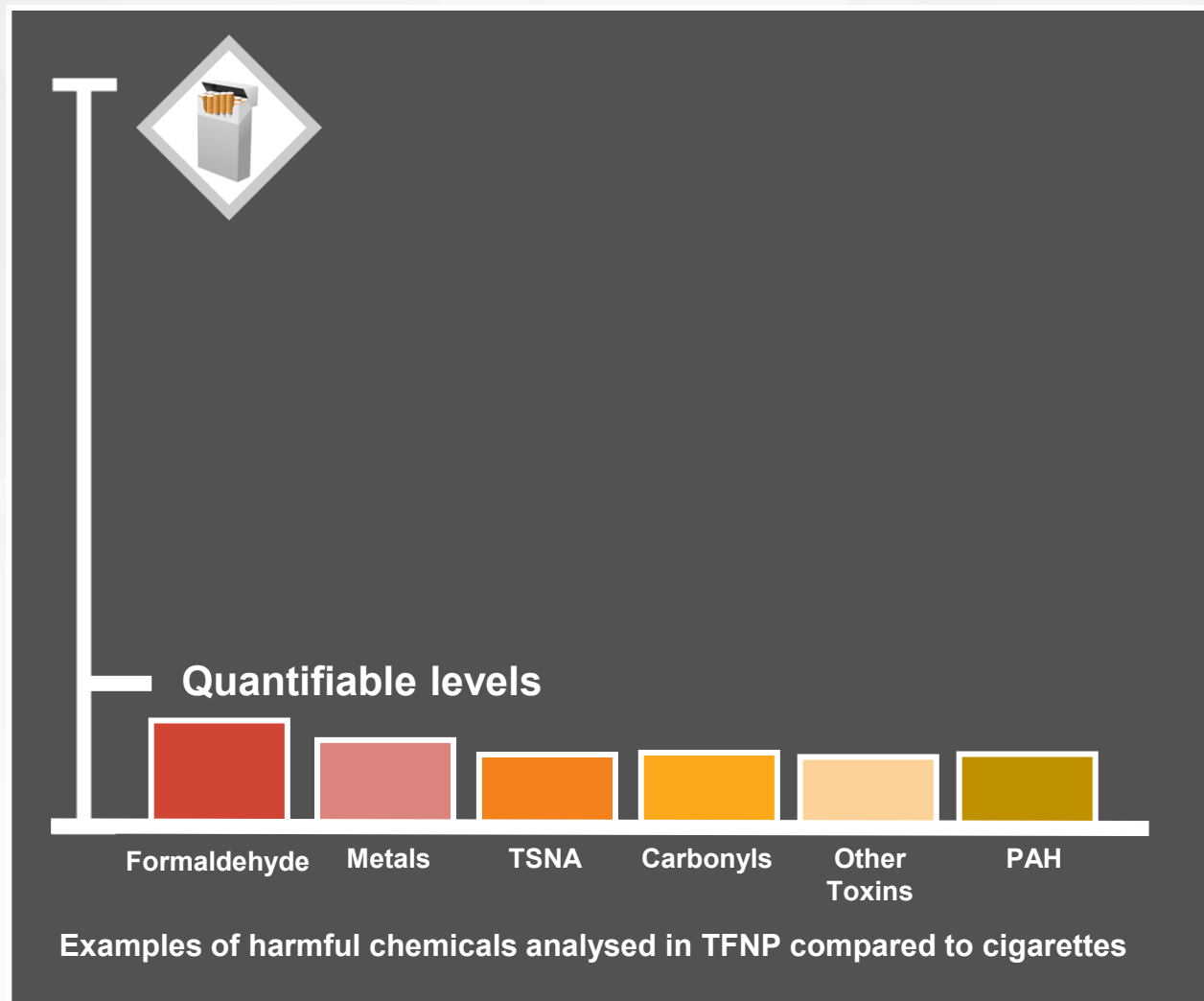
Review's key findings and conclusions



Assessment
of any relevant
effects at both
individual and
population
levels

Chemical and Toxicological analysis

Research indicates TFNP may substantially reduce exposure to harmful chemicals and have lower toxicological impact compared to cigarettes



TFNP may offer an even greater THR than snus as they do not contain tobacco

Clinical studies and subjective effects

TFNP may provide a lower “abuse liability” than cigarettes and facilitate switching to potentially less harmful nicotine products



CRAVING

**URGES TO
SMOKE**

WITHDRAWAL

Illustrative example of Nicotine Pharmacokinetic data for TFNP and cigarettes adapted from Chapman et al., 2022 (IMB study)

Biomarkers and risk of disease

Data are suggestive of a positive individual health benefit when consumers completely switch from combusted or non-combusted tobacco products to TFNP

BIOMARKERS REDUCED	
	
	
	
	
	

FAVOURABLE
CHANGES

LIMITED NUMBER
OF STUDIES

CURRENT DATA CAN
SUPPORT THR

Research suggests that TFNP have compelling THR potential as they are appealing to adult smokers but not unintended populations

ADULTS



Prevalence of use is low, but growing



Regional & cultural differences reported



Appealing to adult smokers but not never smokers



Understanding of relative risk vs other nicotine products

YOUTH



Low prevalence of use and interest in using TFNP



ASSESSMENT IN OTHER COUNTRIES

ASSESSMENT OVER TIME

DIFFERENT ETHNICITY & BACKGROUND



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Summary of reported scientific results

TFNP may have lower chemical and toxicological impact compared to cigarettes, and even traditional snus

Biomarker data suggest that exclusively use of TFNP may lead to a reduced risk of harm to health

TFNP can provide satisfactory nicotine delivery, reduce “abuse liability” & generate positive subjective effects in adult smokers seeking an alternative to cigarettes

TFNP prevalence of use is low among youth (data from US and Netherlands surveys) and low but growing among adult smokers

TFNP predominantly appeal to, and are used by, existing users of combustible and non-combustible tobacco products

Future areas of focus

Further scientific research and public health advocacy of these products is fully warranted



- ❖ Understand the risk characterisation of TFNP as an **alternative to cigarettes** for current adult smokers who start using them
- ❖ Continue monitoring prevalence of use among those who have **never used nicotine products**
- ❖ Continue monitoring how the **use of descriptors on product packaging and marketing materials** may influence curiosity, intentions and motivation to use, and actual use among adult smokers

Conclusions

The literature reviewed indicate that TFNP have the potential to support THR efforts and may help inform evidence-based regulation



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