



# Tobacco Harm Reduction and Novel Nicotine and Tobacco Products

## Evidence from the Japanese Market

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# The application of harm reduction principles to tobacco use has been stimulated by the development and commercial launch of novel nicotine and tobacco products (NNTPs), such as e-cigarettes and heated tobacco products (HTPs).

Harm reduction refers to a set of policies and measures that seek to reduce the level of harm resulting from risky or socially contested behaviours and practices. Harm reduction recognises that eliminating these behaviours and practices from society may not be practically possible, and instead seeks to reduce the total level of harm at individual and population levels.

In recent years, the application of harm reduction principles to tobacco use (tobacco harm reduction or THR) has been stimulated by the development and commercial launch of novel nicotine and tobacco products (NNTPs), such as e-cigarettes and heated tobacco products (HTPs) (sometimes known as heat-not-burn (HnB) products). They are viewed by some public health bodies as likely to be less harmful than inhaling the combustion products in conventional cigarette smoke.<sup>1</sup> Therefore, the use of NNTPs may be seen as a way to reduce risk in smokers who fully switch to them and, if many smokers make that switch, reduce the aggregate level of harm in society caused by smoking.

Harm reduction in tobacco use addresses an issue of enormous importance. Globally, smoking is the leading preventable cause of premature mortality and morbidity: over 7 million people per year die from a smoking-related disease, with a further 1.2 million from exposure to tobacco smoke.<sup>2</sup>

Some (mainly high-income) countries have significantly reduced smoking rates in recent decades (although progress has sometimes slowed and disparities within populations persist). At the same time, smoking has increased in many lower- and middle-income countries, which now account for 80% of tobacco users.<sup>3</sup> As a result, the aggregate number of tobacco users worldwide has declined only marginally, from 1.4 billion in 2000 to 1.34 billion in 2018.<sup>4</sup>

Although smoking rates are relatively higher in developing countries, the significant reductions in smoking rates seen in recent decades seem to be stalling in many developed countries. The use of regulated NNTPs may be an appropriate intervention to reduce the harm that this significant incidence of smoking is causing, and NNTPs are now legally available in many countries worldwide.

In several countries, the use of regulated NNTPs is seen as an appropriate alternative for smokers who will not or cannot quit, and their use for this group is encouraged by public health bodies. For example, in the UK, Public Health England's 'Stoptober' campaign (which encourages smokers to quit each October) recommends that cigarette smokers use e-cigarettes to help them quit.<sup>5</sup> New Zealand's Health Promotion Agency has adopted a similar approach.<sup>6</sup>

<sup>1</sup>For example, Public Health England, see Vaping in England: 2020 evidence update summary, 4 March, 2020, accessed from <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary>

<sup>2</sup>World Health Organization (WHO), Tobacco, accessed from <https://www.who.int/news-room/fact-sheets/detail/tobacco>

<sup>3</sup>WHO, accessed from <https://www.who.int/news-room/fact-sheets/detail/tobacco>

<sup>4</sup>WHO, accessed from <https://www.who.int/news-room/detail/19-12-2019-who-launches-new-report-on-global-tobacco-use-trends>

<sup>5</sup>Pharmaceutical Journal, Stoptober campaign backs e-cigarettes for the first time, 26 September 2017, accessed from <https://www.pharmaceutical-journal.com/news-and-analysis/news/stoptober-campaign-backs-e-cigarettes-for-the-first-time/20203620.article?firstPass=false>

<sup>6</sup>Health Promotion Agency, Vape to Quit campaign, accessed from <https://newsletter.hpa.org.nz/campaigns/reports/viewCampaign.aspx?d=r&c=BAE1E0C2C9F2C8BA&ID=2EB39A15556AB7A72540EF23F30FEDED&temp=False&tx=0>



However, the role of NNTPs in public health policy remains controversial, with significant concerns remaining about their short-term and long-term effects. The World Health Organization (WHO), for example, raises concerns about the lack of long-term data on their impact on health and on the short-term potential for never-smoker youth to start using NNTPs such as e-cigarettes and later transition to smoking conventional cigarettes.<sup>7</sup> In several developed countries, such as Australia and Singapore, the sale of NNTPs is still largely illegal. A recent review, for example, by the Australian government concluded that HTPs should remain largely unavailable (except with a medical prescription) on the basis that the regulator “*is not persuaded that HTPs would not attract ‘never smokers’ including youth*”, and that the regulator is “*not satisfied that there is a net public health benefit from wider availability of nicotine in the form of HTPs.*”<sup>8</sup>

There are also questions about the effectiveness of NNTPs in supporting smokers to quit conventional cigarettes entirely or whether many users would use both NNTPs and conventional cigarettes in parallel (dual-use), which would significantly mitigate any health benefits that NNTPs bring, particularly if overall consumption of conventional cigarettes remains largely unchanged.

The country which has witnessed the largest switching of smokers to NNTPs is Japan, although Japan has no formal THR policy to encourage this. While the impact of NNTPs on smoking in Japan may be relatively unknown internationally, it merits greater scrutiny and debate. This white paper describes the impact of the commercial launch of NNTPs on tobacco use in Japan, and discusses the regulatory approach that the Japanese government is taking to NNTPs.

<sup>7</sup>WHO, E-cigarettes are harmful to health, accessed from <https://www.who.int/news-room/detail/05-02-2020-e-cigarettes-are-harmful-to-health>

<sup>8</sup>Australian Department of Health, Therapeutic Goods Administration, Notice of final decisions to amend (or not amend) the current Poisons Standard, 24 August 2020.

## THE THEORY OF THR

**There is increasing scientific evidence that NNTPs are a better alternative to cigarettes for adult smokers who would otherwise continue to smoke.**

THR is dependent on the relative degree of risk that alternatives such as NNTPs present when compared to conventional cigarettes, as well as the degree to which smokers accept alternative products as a replacement for

conventional cigarettes, which will determine the number of smokers that switch to NNTPs. This can be summarised as a basic equation, as shown in Figure 1.

Figure 1: The Tobacco Harm Reduction Equation



Source: Clive Bates, Regulation, when less is more, presentation to E-cigarette Summit, 2013, accessed from <https://www.slideshare.net/lindsayfox/clive-bates-e-cigarette-summit>

There is increasing scientific evidence that NNTPs are a better alternative to cigarettes for adult smokers who would otherwise continue to smoke. Slob et al. compared the impact on carcinogenicity of HTPs and cigarettes by

focusing on the change in cumulative exposure (CCE) of the compounds emitted by HTPs and cigarettes and concluded that *"the CCE was estimated to be 10- to 25-fold lower when using HTPs instead of cigarettes."*<sup>9</sup>

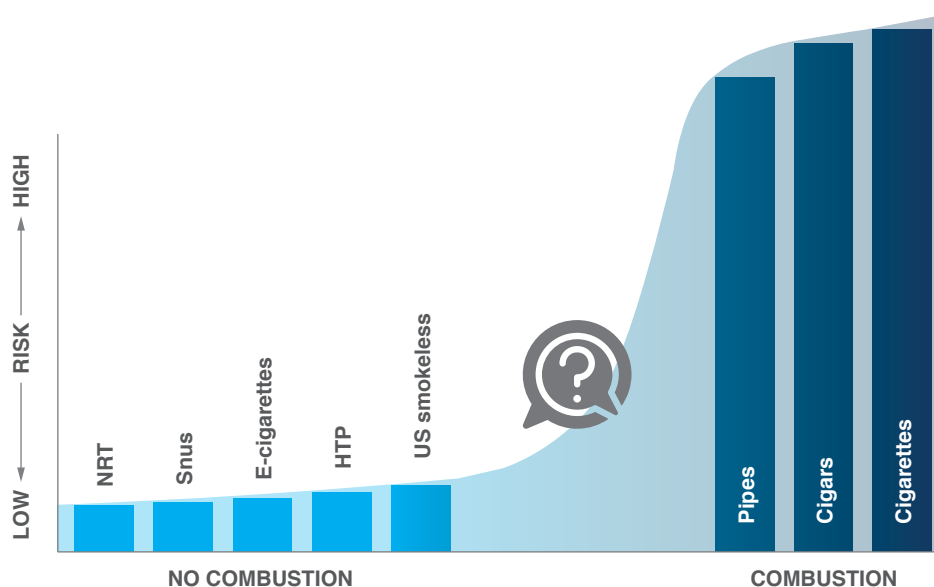
<sup>9</sup>Slob et al., A Method for Comparing the Impact on Carcinogenicity of Tobacco Products: A Case Study on Heated Tobacco Versus Cigarettes, Risk Analysis, Vol. 40, No. 7, 2020, DOI: 10.1111/risa.13482.

A recent meta-analysis by Australian researchers on the safety of novel tobacco products “found that the potential for harm to humans is reduced when using HnB devices compared to CC (conventional cigarettes) as indicated by significant reductions in biomarkers-of-exposure (BoE) levels. Whilst these results support tobacco manufacturer claims of improved safety, the small number of studies included, limited range of BoE assessed, and involvement of the tobacco industry necessitate further independent research to confirm the HnB devices as being a safer alternative to CC.”<sup>10</sup> A review by the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on the potential toxicological risks from e-cigarettes (defined as electronic nicotine (and non-nicotine) delivery systems (E(N)NDS)) concluded that when comparing use of E(N)NDS to conventional cigarettes (CC), “the relative risk of adverse health effects would be expected to be substantially lower from E(N)NDS. This risk reduction would occur if people who are already smoking CC switch to E(N)NDS, or if E(N)NDS are taken up instead of CC.”<sup>11</sup>

Many public health experts advocate that governments adopt the policy of THR to complement the other major strategies for reducing smoking-related harm (i.e., prevention and cessation). Furthermore, many public health authorities agree that there is a broad continuum of risk among tobacco and nicotine-containing products, such as the US Food and Drug Administration (FDA).<sup>12</sup> This continuum recognises that most of the harm caused by tobacco results from the burning of tobacco. NNTPs and other nicotine-containing products are therefore differentiated from the risk associated with conventional tobacco products and placed close to the lower end of risk on this risk continuum.

The relative level of harm presented by conventional cigarettes and a range of alternatives is summarised in Figure 2. The continuum of risk for nicotine-containing products has cigarettes at the high-risk end. Smokeless tobacco products such as Swedish Snus, NNTPs such as e-cigarettes and HTPs, as well as nicotine replacement therapies (NRTs), are on the lower end of the risk continuum.

**Figure 2: Harm Continuum in Nicotine Products**



Source: Global State of Tobacco Harm Reduction, accessed from <https://gsthr.org/resources/item/burning-issues-global-state-tobacco-harm-reduction-2020>

<sup>10</sup>Drovandi et al., Human Biomarker Exposure From Cigarettes Versus Novel Heat-Not-Burn Devices: A Systematic Review and Meta-Analysis, *Nicotine Tob Res.* 2020 Jun 12;22(7):1077-1085. doi: 10.1093/ntr/ntz200.

<sup>11</sup>UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes).

<sup>12</sup>FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death, 27 July 2017, accessed from <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>

## THR OUTSIDE JAPAN

The use of NNTPs as a means to achieve tobacco harm reduction is supported by regulatory authorities in various countries:

**In the UK**, for example, the use of e-cigarettes (vaping) as an alternative to smoking has been endorsed by the government and medical professionals. Research from Public Health England (PHE),<sup>13</sup> subsequently endorsed in a report by the Royal College of Physicians (RCP),<sup>14</sup> concluded that vaping is less harmful than smoking cigarettes. The government policy for England is to *“help people to quit smoking by permitting innovative technologies that minimise the risk of harm and maximise the availability of safer alternatives to smoking.”*<sup>15</sup> Moreover, recent research on the UK market has indicated that declines in England’s smoking rate from 2012 to 2019 coincided with the introduction of e-cigarettes, with the implied reduction in smoking prevalence equating to 165,660 averted deaths by 2052.<sup>16</sup> PHE has recently re-emphasised the potential role of NNTPs in reducing the smoking health burden - *“despite reductions in smoking prevalence, smoking remains the biggest single cause of preventable death and disease and a leading cause of health inequalities. So, alternative nicotine delivery devices that are less harmful could play a crucial role in reducing this health burden.”*<sup>17</sup> A 2020 survey commissioned by Action on Smoking and Health (ASH) on the use of e-cigarettes (vapes) among adults in Great Britain identified that an estimated 6.3% of the adult population (3.2 million people) currently use e-cigarettes; however, *“use of e-cigarettes is largely confined to current and ex-smokers and use amongst never smokers remains low”* with only 100,000 of all current e-cigarette users (2.9%) being never smokers. Among all e-cigarette users, the three main reasons for vaping are as an aid to quitting (30%), followed by preventing relapse (20%), and to cut down the number of cigarettes smoked (11%).<sup>18</sup>

**In the US**, *“harnessing new forms of nicotine delivery that could allow currently addicted adult smokers to get access to nicotine without all the risks associated with using combustible tobacco products”*<sup>19</sup> is a core element of the government’s plan on tobacco and nicotine regulation announced in 2017. In July 2020, the FDA authorised the marketing of the IQOS brand of HTPs from Philip Morris International (PMI) as a *“modified risk tobacco product (MRTP)” with a claim of reduced exposure on the basis that “they could help addicted adult smokers transition away from combusted cigarettes and reduce their exposure to harmful chemicals, but only if they completely switch.”*<sup>20</sup> While the FDA acknowledged concerns about whether users will switch completely from conventional cigarettes, and whether they will cause increased use amongst youth, it decided to issue the order on the basis that IQOS *“is expected to benefit the health of the population as a whole.”*<sup>21</sup> The FDA has also issued MRTP orders in respect of Snus products.

**In New Zealand**, the Health Promotion Agency worked with the Ministry of Health to prepare information for the public on vaping, including a dedicated website which explains that vaping is much less harmful than smoking.<sup>22</sup> The government has also recently legislated to regulate vaping, seeking to balance the need to prevent non-smokers (particularly children and young people) from starting to vape, with the need to support smokers to switch to regulated products that are significantly less harmful than smoking.<sup>23</sup>

<sup>13</sup>UK government press release, 19 August 2015, accessed from <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

<sup>14</sup>Royal College of Physicians, Nicotine without smoke: Tobacco harm reduction , accessed from <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>

<sup>15</sup>See page 24 of Public Health England’s evidence review, March 2020, accessed from [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/869401/Vaping\\_in\\_England\\_evidence\\_update\\_March\\_2020.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869401/Vaping_in_England_evidence_update_March_2020.pdf)

<sup>16</sup>Levy et al., England SimSmoke: The Impact of Nicotine Vaping on Smoking Prevalence and Smoking-Attributable Deaths in England, doi: 10.1111/add.15269

<sup>17</sup>Public Health England, Vaping in England: 2020 evidence update summary, March 2020, accessed from <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary>

<sup>18</sup>Action on Smoking and Health, Use of e-cigarettes (vapes) among adults in Great Britain, October 2020, accessed from <https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf>

<sup>19</sup>Statement from FDA Commissioner Scott Gottlieb, March 2019, accessed from <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-actions-advance-our-comprehensive-plan-reduce-tobacco>

<sup>20</sup>FDA, FDA Authorizes Marketing of IQOS Tobacco Heating System with ‘Reduced Exposure’ Information, July 7 2020, accessed from <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>

<sup>21</sup>Ibid.

<sup>22</sup>Ministry of Health, Health Promotion Agency, Vaping vs. Smoking, accessed from <https://www.vapingfacts.health.nz/vaping-vs-smoking/>

<sup>23</sup>New Zealand Legislation, Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020, accessed from <http://www.legislation.govt.nz/act/public/2020/0062/40.0/LMS313921.html>

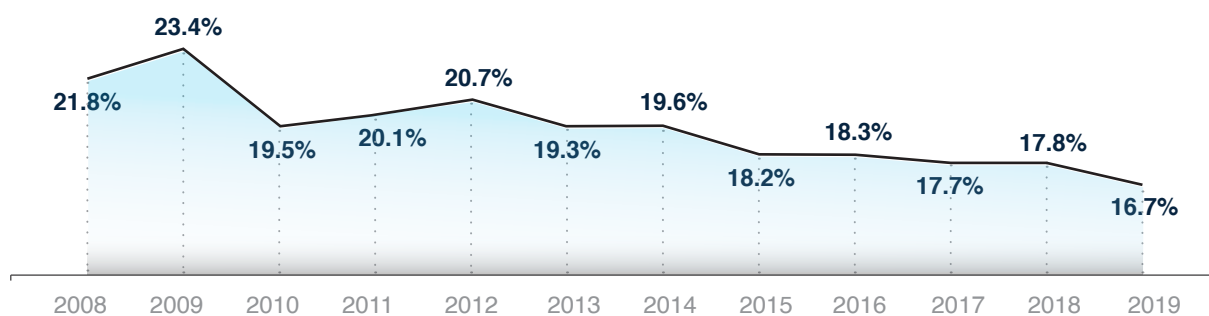
## DATA FROM JAPAN

### TOBACCO USE IN JAPAN

In recent years, overall tobacco use (including cigarette smokers and HTP users) in Japan has declined, in line with the trend in other developed economies. From 21.8% of the adult population who used tobacco in 2008, the

overall tobacco use declined to 16.7% in 2019. Nonetheless, the rate of decline has slowed in recent years, and 18.8 million Japanese still used tobacco in 2018.<sup>24</sup>

**Figure 3: Overall Tobacco Use (Cigarette and HTP Use), Japan, 2008 to 2019**

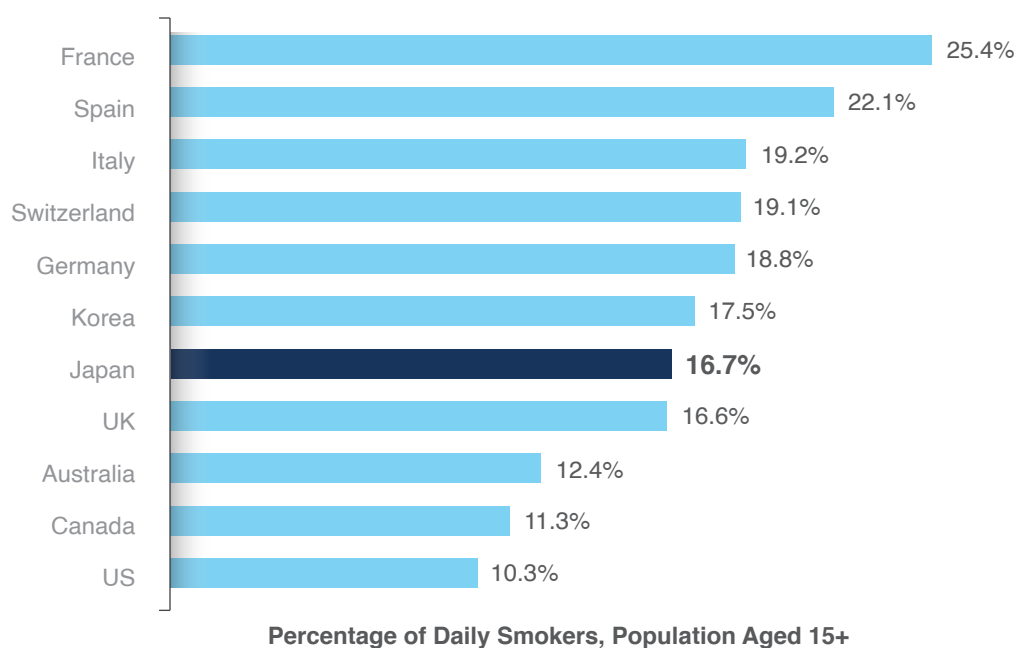


Source: National Health and Nutrition Survey, 2019

In comparison, Japan's overall tobacco use of 16.7% places it well behind countries such as Australia, Canada, and the US, but ahead of many high-income European

countries, including France, Spain, Italy, Switzerland and Germany.<sup>25</sup>

**Figure 4: Daily Smoking Rate by Country**



Source: Organisation for Economic Cooperation and Development (OECD), Daily Smokers (accessed from <https://data.oecd.org/healthrisk/daily-smokers.htm>). Japan National Health and Nutrition Survey, 2019. Data is for 2019 or the latest available year.

<sup>24</sup>Japan Tobacco, press release, 2018, accessed from [https://www.jt.com/media/news/2018/pdf/20180730\\_02.pdf](https://www.jt.com/media/news/2018/pdf/20180730_02.pdf)

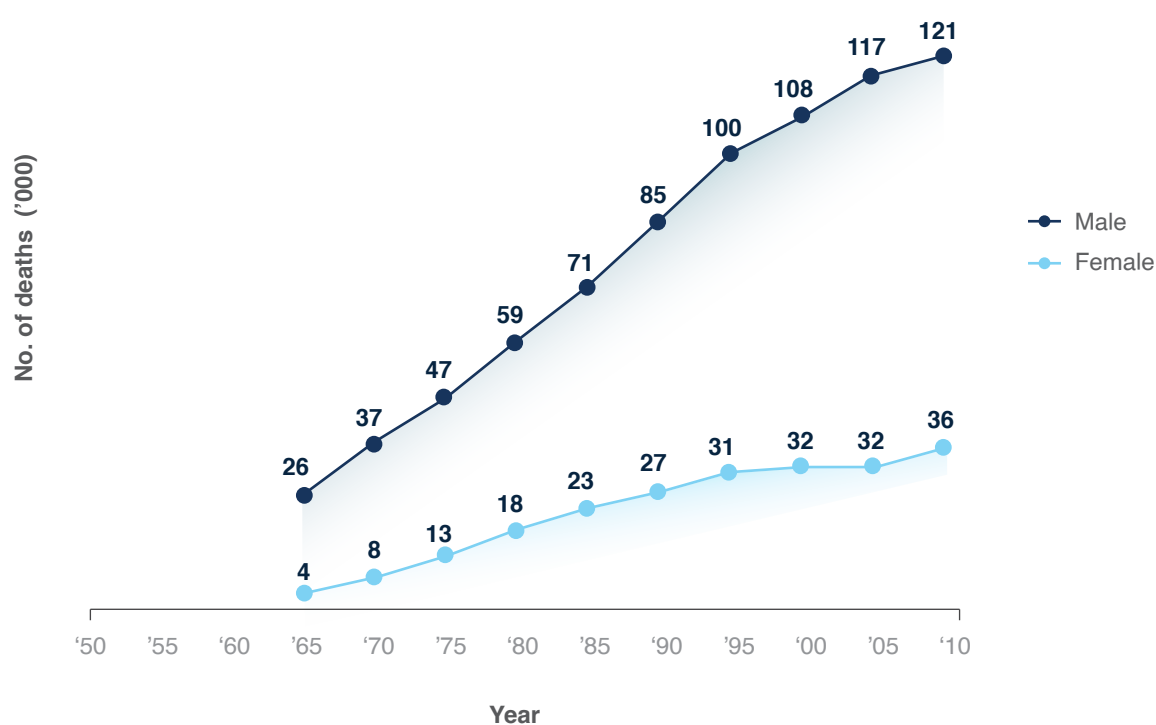
<sup>25</sup>Organisation for Economic Cooperation and Development (OECD), Daily Smokers, accessed from <https://data.oecd.org/healthrisk/daily-smokers.htm>



Smoking places a significant health burden on Japan and is the single largest cause of death, accounting for 157,000 deaths in 2010, compared to 140,000 in 2000.<sup>26</sup> Twenty-six per cent of regular smokers wish to quit,<sup>27</sup>

but the smoking cessation success rate is only about 27%, indicating that the current means of quitting are not working for many smokers.<sup>28</sup>

**Figure 5: Number of Smoking-related Deaths, Japan, 1965 to 2010**



Source: Petro et al., Mortality from Smoking in Developed Countries, 1950-2020, Japan, accessed from <https://gas.ctsu.ox.ac.uk/tobacco/C3160.pdf>

NNTPs, therefore, have a potential role in THR in Japan, providing that they are sufficiently acceptable to smokers that they switch completely. Evidence that this is occurring could be obtained from data on cigarette sales, as well as surveys on the usage of NNTPs and conventional cigarettes.

Data from Japan can also provide insights on the degree to which smokers switch completely to NNTPs, and whether the availability of NNTPs results in never smokers or ex-smokers initiating or re-initiating tobacco use.

<sup>26</sup>Petro et al., Mortality from Smoking in Developed Countries, 1950-2020, Japan, accessed from <https://gas.ctsu.ox.ac.uk/tobacco/C3160.pdf>

<sup>27</sup>National Health and Nutrition Survey, 2019, accessed from <https://www.mhlw.go.jp/content/10900000/000687163.pdf>

<sup>28</sup>Central Social Insurance Medical Council, Ministry of Health's Advisory Board, accessed from <https://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000184202.pdf>

The commercial availability of NNTPs (specifically HTPs) in Japan allows the analysis of their impact in a real-market situation. This includes the degree to which existing smokers have switched to the use of HTPs, which would manifest in a reduction in cigarette consumption, as well as the degree to which never smokers (particularly youth) or former smokers have initiated or re-initiated tobacco consumption through HTPs.

Japan is the largest global market for HTPs, accounting for an estimated 85% share of the global market, and can provide useful guidance to other countries on the market impact of HTPs.<sup>29</sup> Based on the 2019 Japan National Health and Nutrition Survey, 27.2% of male tobacco users and 25.2% of female tobacco users use HTPs.<sup>30</sup>

### IMPACT ON CIGARETTE SALES

**It is likely that the introduction of HTPs in Japan has caused a significant decline in cigarette sales, well above the previous rate of decline.**

The first HTP brand introduced in Japan was Ploom by Japan Tobacco in December 2013 (although this was discontinued and a new product, PloomTECH, was launched in 2016), followed by IQOS from PMI. Although IQOS was first available in Japan from 2014 with a limited launch in selected stores in Nagoya, its wider commercial roll-out was staggered by prefecture, with launch in 12 prefectures in September 2015 and in the remaining 35 prefectures in April 2016. This has allowed Stoklosa et al. to compare changes in cigarette sales between prefectures where HTPs became available against those where they were not yet available by examining the sales data of tobacco products from supermarkets and convenience stores in different regions of Japan between 2014 and 2018. Although per capita conventional cigarette

sales had shown a slight increase prior to 2015, they began to decline following the launch of IQOS, with the decline starting earlier in all prefectures where IQOS was first introduced. Based on dates of the IQOS launch and trends in cigarette sales, Stoklosa et al. concluded that as a result of the introduction of HTPs in Japan, *“cigarette consumption has likely been reduced”*. Moreover, the introduction of HTPs has not caused an increase in overall sales of tobacco products, with aggregate consumption of tobacco products continuing to fall, as can be seen in Figure 6. Stoklosa et al. cautioned that the *“net population health impact, however, cannot be assessed without resolving several key uncertainties related to the direct harms of IQOS and the precise patterns of both smoking and IQOS use.”*<sup>31</sup>

**Between 2015 and 2019, total cigarette sales dropped by 34%.**

Cummings et al. also reported that from 2011 to 2016, sales of cigarettes declined by about 2% to 4% annually, while a decline of 13% in cigarette sales occurred in 2017, 12% in 2018, and 9% in 2019, indicating a much more significant decline over this period. Between 2015 and 2019, total cigarette sales dropped by 34%.<sup>32</sup>

Over this time, sales of HTPs increased from 5.1 billion sticks to 37.1 billion. When sales of HTPs are included in

the analysis, the decline in sales in tobacco products was in line with the longer-term trend. This suggests that the significant decline in cigarette sales from 2015 is likely due to users switching to HTPs as these products were introduced in Japan. Cummings et al. also concluded that *“the accelerated decline in cigarette-only sales in Japan since 2016 corresponds to the introduction and growth in the sales of HTPs.”*<sup>33</sup>

<sup>29</sup>Reuters, Philip Morris aims to revive Japan sales with cheaper heat-not-burn tobacco, accessed from <https://www.reuters.com/article/us-pmi-japan/philip-morris-aims-to-revive-japan-sales-with-cheaper-heat-not-burn-tobacco-idUSKCN1MX06E>

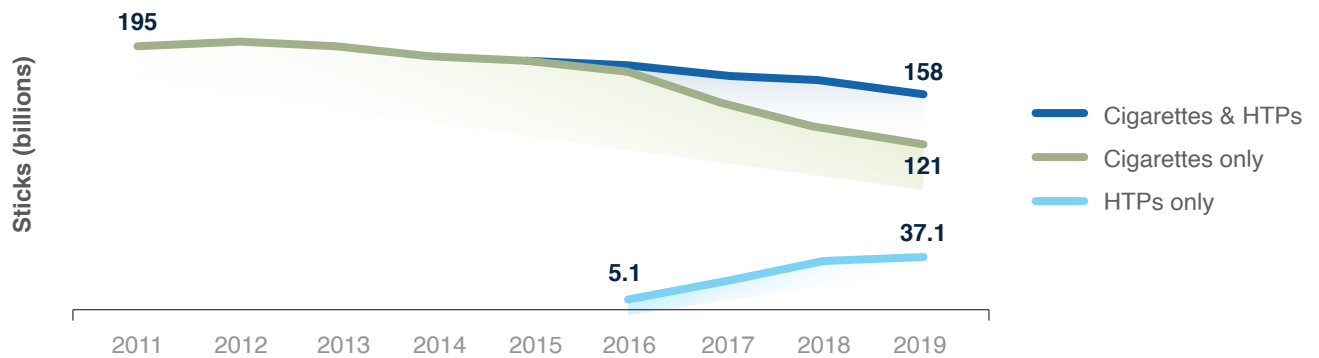
<sup>30</sup>National Health and Nutrition Survey, 2019, accessed from <https://www.mhlw.go.jp/content/10900000/000687163.pdf>

<sup>31</sup>Stoklosa, M., Cahn, Z., Liber, A., et al. Effect of IQOS introduction on cigarette sales: evidence of decline and replacement, *Tob Control* 2020;29:381–387.

<sup>32</sup>Cummings et al., What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?, *Int. J. Environ. Res. Public Health* 2020, 17, 3570; doi:10.3390/ijerph17103570.

<sup>33</sup>Ibid.

**Figure 6: Sales of Tobacco Products, Japan, 2011 to 2019**



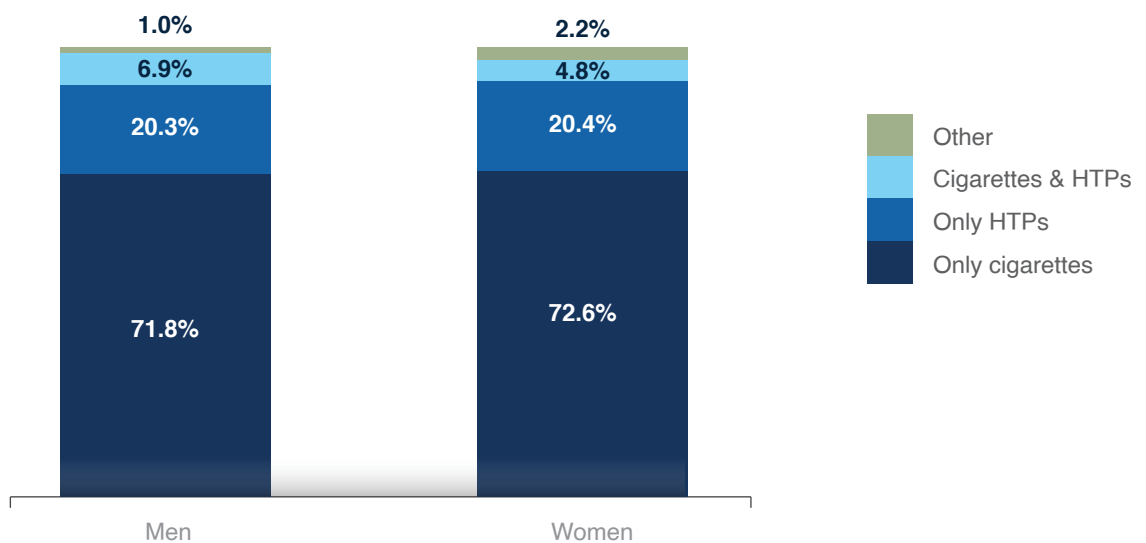
Source: PCummings et al., What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?, *Int. J. Environ. Res. Public Health* 2020, 17, 3570; doi:10.3390/ijerph17103570

## UPTAKE BY SMOKERS AND DUAL-USE

A key uncertainty around NNTPs is the degree to which smokers will switch completely or continue to use conventional cigarettes in parallel (dual-use), lowering the potential harm reduction benefit of NNTPs. There is mixed evidence on this issue. Based on a weighted survey of 8,240 individuals aged 15-69, Hori et al. concluded that HTP use amongst the Japanese population was 11.3% in 2019, with almost 80% of HTP users being current smokers (i.e., dual users).<sup>34</sup> However, based on the 2019 Japan National Health and Nutrition Survey, amongst

tobacco users, a significant majority use only cigarettes or only HTPs, with dual-use limited to about 6% of all tobacco users. This indicates that among those who use HTPs, about 76% have switched completely to HTPs and no longer use conventional cigarettes. In other words, about 24% of HTP users are dual-users.<sup>35</sup> Similarly, based on a cross-sectional epidemiological survey administered in Sendai, Tokyo, and Osaka, from May 19 to June 25, 2018, Adamson et al. concluded that only 10.5% of current tobacco users are dual users.<sup>36</sup>

**Figure 7: Use of Tobacco Products, Japan, 2019**



Source: National Health and Nutrition Survey, 2019

<sup>34</sup>Hori, A., Tabuchi, T., Kunugita, N., Rapid increase in heated tobacco product (HTP) use from 2015 to 2019: from the Japan 'Society and New Tobacco' Internet Survey (JASTIS), *Tob Control* 2020;0:1-2. doi:10.1136/tobaccocontrol-2020-055652

<sup>35</sup>National Health and Nutrition Survey, 2019, accessed from <https://www.mhlw.go.jp/content/10900000/000687163.pdf>

<sup>36</sup>Adamson, J., Kanitscheider, C., Prasad, K. et al. Results from a 2018 cross-sectional survey in Tokyo, Osaka and Sendai to assess tobacco and nicotine product usage after the introduction of heated tobacco products (HTPs) in Japan. *Harm Reduct J* 17, 32 (2020), <https://doi.org/10.1186/s12954-020-00374-3>

## INITIATION OR RE-INITIATION

The extent to which never smokers may be attracted to and initiate tobacco/nicotine use through NNTPs is an ongoing question, with the risk of nicotine addiction subsequently causing the user to transition to conventional cigarettes. The potential for youth never smokers to initiate through these products is a matter of particular concern. Additionally, ex-smokers who have successfully quit may re-initiate tobacco/nicotine use through NNTPs.

### Youth usage

Japanese government-commissioned data indicates low usage of HTPs by middle school and high school students. Only 0.1% of students at middle schools and high schools were using HTPs daily, with daily use of HTPs by high school students one-fifth of the rate of conventional cigarettes.<sup>37</sup>

**Figure 8: Use of Tobacco Products by Youth, Japan, Dec. 2017 to Feb. 2018**

Use	Cigarettes			HnB			E-Cigarettes		
	Ever	Monthly	Daily	Ever	Monthly	Daily	Ever	Monthly	Daily
Middle School	2.6%	0.6%	0.1%	1.1%	0.5%	0.1%	2.1%	0.7%	0.1%
High School	5.1%	1.5%	0.5%	2.2%	0.9%	0.1%	3.5%	1.0%	0.1%

Note: Monthly refers to use in the preceding month.

Source: Yoneatsu Osaki, Chief investigator, Professor, Division of Environmental and Preventive Medicine, Faculty of Medicine, Tottori University, accessed from <https://mhlw-grants.niph.go.jp/niph/search/NIDD00.do?resrchNum=201709021A>

The evidence from Japan with respect to HTPs is consistent with surveys on vaping in both the UK and New Zealand:

- 1 In England, regular vaping (i.e., weekly or more often) among 15-year-olds was estimated at 3.9%.<sup>38</sup> Vaping in young people was most prevalent among regular smokers and rare among never smokers. Less than 1% of never smokers identified as regular vapers. Even when including experimental users, the proportion of young people who tried vaping before smoking was 17.8% in 2019.<sup>39</sup>
- 2 In New Zealand, 3.1% of Year 10 (age 14-15) students vaped daily. However, this figure was much lower among those who had never smoked, as in the UK. Only 0.8% of Year 10 students who had never smoked reported vaping daily.<sup>40</sup>

<sup>37</sup>Yoneatsu Osaki, Chief investigator, Professor, Division of Environmental and Preventive Medicine, Faculty of Medicine, Tottori University, accessed from <https://mhlw-grants.niph.go.jp/niph/search/NIDD00.do?resrchNum=201709021A>

<sup>38</sup>Public Health England (PHE), accessed from [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/869401/Vaping\\_in\\_England\\_evidence\\_update\\_March\\_2020.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869401/Vaping_in_England_evidence_update_March_2020.pdf)

<sup>39</sup>Ibid.

<sup>40</sup>Walker et al., Use of e-cigarettes and smoked tobacco in youth aged 14–15 years in New Zealand: findings from repeated cross-sectional studies (2014–19) , accessed from [https://doi.org/10.1016/S2468-2667\(19\)30241-5](https://doi.org/10.1016/S2468-2667(19)30241-5)



**The evidence from Japan and some other countries shows that the availability of NNTPs has a low impact on the initiation of tobacco use by never smokers and re-initiation by former smokers.**

### Adult initiation and re-initiation

Information from general population surveys and IQOS user surveys in Japan undertaken by PMI in 2016 and 2017 (wave 1 and wave 2) indicates that the extent of initiation or re-initiation is minimal. Based on the general population survey, 99.1% of ever tobacco product users had initiated tobacco use through cigarettes, and only 0.5% through IQOS (wave 2). Less than 0.1% of ex-smokers (defined as individuals who had stopped smoking more than two years previously) had re-initiated tobacco use through IQOS.<sup>41</sup>

Separate research on IQOS usage indicated that current smokers with the intention to quit were significantly more likely to use IQOS than current smokers with no intention to quit (18.8% versus 10.3%). Conversely, being a never smoker or a former smoker is a poor indicator of the likelihood of IQOS usage. The adjusted odds ratio (AOR)<sup>42</sup>

of IQOS use amongst current smokers with the intention to quit is 13.3 and 6.74 for current smokers with no intention to quit, compared to 1.79 for former smokers and 1.0 for never smokers.<sup>43</sup>

Concerns over never smoker tobacco initiation or ex-smoker re-initiation as a result of the availability of NNTPs are not supported by data from Japan. This supports conclusions drawn from other countries. In Great Britain, for example, among all e-cigarette users (3.2 million), only 100,000 are never smokers.<sup>44</sup>

Overall, the evidence from Japan and some other countries shows that the availability of NNTPs has a low impact on the initiation of tobacco use by never smokers and re-initiation by former smokers.

<sup>41</sup>Langer et al., Tobacco product use after the launch of a heat-not-burn alternative in Japan: results of two cross-sectional surveys, poster presentation, GFN Warsaw, 2019, accessed from [https://www.pmiscience.com/resources/docs/default-source/posters2019/langer-2019-tobacco-product-use-after-the-launch-of-a-heat-not-burn-alternative-in-japan.pdf?sfvrsn=460ed806\\_4](https://www.pmiscience.com/resources/docs/default-source/posters2019/langer-2019-tobacco-product-use-after-the-launch-of-a-heat-not-burn-alternative-in-japan.pdf?sfvrsn=460ed806_4)

<sup>42</sup>AOR is an odds ratio that controls for other predictor variables in a model.

<sup>43</sup>Tabuchi, T., Gallus, S., Shinozaki, T., et al. *Tob Control* 2018;27:e25–e33.

<sup>44</sup>Action on Smoking and Health, Use of e-cigarettes (vapes) among adults in Great Britain, October 2020, accessed from <https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf>

## REGULATION OF NNTPS IN JAPAN

Japan has a mixed approach to the regulation of NNTPs. e-cigarettes containing nicotine are regulated by the Ministry of Health and are regarded as a pharmaceutical product. HTPs are regarded as a tobacco product as their components are made of tobacco leaf and are regulated by the Ministry of Finance.

Nicotine-containing e-cigarette products are not currently legally available in Japan. They are restricted by the Pharmaceutical Affairs Law of 2010.

Under this law, e-cigarettes are defined as medicinal products, and approval for their sale, advertisement, manufacture, importation, and distribution must be obtained. To date, no e-cigarette products have been approved, although there is an allowance for the private importation of nicotine liquid of up to one month's supply.<sup>45</sup> e-cigarette products that do not contain nicotine are not subject to this law and are freely available in Japan.

Figure 9: Regulation of NNTPs, Japan, 2020



Source: Hiroya Kumamaru, M.D., Presentation to Global Tobacco and Nicotine Forum, 2020

**The regulatory framework for HTPs is increasingly diverging from the framework governing conventional cigarettes, including in terms of taxation, health warnings and restrictions on use.**

HTPs are included within the Tobacco Business Act 1984, which makes HTPs legally saleable in Japan. They have been available nationwide since 2016.

Whilst HTPs are included within the Tobacco Business Act, their regulatory framework is increasingly diverging from the framework governing conventional cigarettes, including in terms of taxation, health warnings and restrictions on use.

<sup>45</sup>Global Tobacco Control, Country Laws Regulating e-cigarettes, Japan, accessed from <https://www.globaltobaccocontrol.org/e-cigarette/japan>



## Customs and excise taxation

When first introduced, there was no taxation category for HTPs, and they were taxed on the same basis as pipe tobacco, driven by an initial customs classification assessment under pipe tobacco with customs code 2403.19. This was later changed to a customs code of 2403.99, a “residual” customs code for tobacco products that cannot be classified in any of the separately identified categories. Excise taxation of pipe tobacco is linked to conventional cigarettes, with an equivalence rate (1g is considered equivalent to one conventional cigarette unit). The tax rate payable depended on the product weight of each HTP unit, including wrapping papers and filters. Product weight as the tax base resulted in tax differences for different brands as the consumed tobacco amount in each product differed. More recently, a new tobacco tax specific for HTPs has been introduced to be fully implemented over five years. The new system is mixed, comprising 50% based on a specific amount per weight of the heated tobacco (excluding the weight of parts pertaining to filters and other items such as wrapping papers) and 50% based on an ad valorem element on the retail price net of sales tax.<sup>46</sup> The new system abolishes the product weight-based taxation and aims to tax the consumables such as tobacco. In addition, unlike many countries, the new system features an ad valorem element.



## Health warnings

The health warnings on HTPs that are required under the Tobacco Business Act are also being differentiated from those on conventional cigarettes. Whilst warnings on conventional cigarettes list the diseases caused by use or passive exposure, the warnings on HTPs only state that the impact on health of heated tobacco smoke (aerosol) cannot be denied.



## Outdoor use

Japan has no national law governing outdoor smoking. However, restrictions on outdoor smoking have been introduced at the local level in many municipalities to reduce the risk of burning bystanders, litter from cigarette butts and smell complaints from smoking. In the 20 major cities, 16 have exempted HTPs from outdoor smoking restrictions since HTPs do not combust, have a lower/negligible risk of burning bystanders, and generate less odour. Additionally, nine out of the 23 Tokyo wards have exempted HTP from outdoor smoking restrictions.



## Indoor use

In terms of indoor smoking, the Health Promotion Law and the Industrial Safety and Health Law place responsibility on facility owners and employers to protect individuals from the impact of passive smoking. Indoor smoking is banned in facilities such as schools, clinics, and government buildings; however, smoking in bars, restaurants and cafes has so far been legal if it is allowed by the owner. The revised Health Promotion Law, which was implemented on April 1, 2020, imposes new regulations on smoking in these types of premises. Smoking in small establishments is allowed as long as the restaurant is designated as a smoking facility (Tokyo has implemented a stricter local ordinance, allowing it only if the establishment is exclusively run by family members). In larger establishments, smoking is allowed only in a dedicated smoking booth in which eating and drinking are not permitted. However, the law regulates the use of HTPs differently, and these may be used in dedicated HTP areas in which eating and drinking are also allowed. The revised Health Promotion Law protects non-smokers from being exposed to secondhand smoke and protects HTP users from being exposed to cigarette smoke. The National Cancer Centre and the Ministry of Health, Welfare and Labour have justified this policy on the basis that “*exposure to aerosol from HTPs in a designated smoking room under usual conditions is estimated to be tolerable since the lifetime cancer risk is expected to be below a virtually safe dose (VSD) of 10–5 (1/100,000), which is three orders of magnitude lower than that for cigarettes smoked under the same conditions*”.<sup>47</sup> Research by Hirano et al. of the Health Service Division, Health Service Bureau, Ministry of Health, Labour and Welfare, also compared the concentration of nicotine and particulate matter (PM2.5) in the air following 50 puffs in the use of HTPs or cigarettes in a small shower cubicle and concluded that “*results do not negate the inclusion of HTPs within a regulatory framework for indoor tolerable use from exposure to HTP aerosol, unlike cigarette smoke*”.<sup>48</sup>

<sup>46</sup>Japan Ministry of Finance, Tax Reform, Tobacco Tax, accessed from [https://www.mof.go.jp/tax\\_policy/tax\\_reform/outline/fy2018/explanation/pdf/p0985-1002.pdf](https://www.mof.go.jp/tax_policy/tax_reform/outline/fy2018/explanation/pdf/p0985-1002.pdf)

<sup>47</sup>Hirano et al., Division of Tobacco Policy Research, Center for Cancer Control and Information Services, National Cancer Center, Estimating the Carcinogenic Potency of Second-Hand Smoke and Aerosol from Cigarettes and Heated Tobacco Products, *Int. J. Environ. Res. Public Health* 2020, 17(22), 8319, accessed from <https://www.mdpi.com/1660-4601/17/22/8319/html>

<sup>48</sup>Hirano et al., Health Service Division, Health Service Bureau, Ministry of Health, Labour and Welfare, Exposure Assessment of Environmental Tobacco Aerosol from Heated Tobacco Products: Nicotine and PM Exposures under Two Limited Conditions, *Int. J. Environ. Res. Public Health* 2020, 17, 8536

Figure 10: Cigarette and HTP Booth Signage, Japan, 2020



Source: Ministry of Health, Labour and Welfare, accessed from [https://www.mhlw.go.jp/stf/houdou\\_kouhou/kouhou\\_shuppan/magazine/201904\\_00015.html](https://www.mhlw.go.jp/stf/houdou_kouhou/kouhou_shuppan/magazine/201904_00015.html)





Policymakers in Japan are increasingly recognising that HTPs are different to conventional cigarettes and are regulating them differently.

**Table 1: Regulation of Conventional Cigarettes and NNTPs, Japan, 2020**

	Conventional Cigarettes	NNTPs	
		HTPs	e-cigarettes
<b>Regulatory Body</b>	<i>Ministry of Finance.</i> Products are designated as tobacco and are legally available	<i>Ministry of Finance.</i> Products are designated as tobacco and are legally available	<i>Ministry of Health.</i> Products are designated as pharmaceuticals and approval is required. No products approved to date
<b>Taxation</b>	Based on the number of cigarette units	Based on the weight of the heated tobacco (excluding the weight of parts pertaining to filters and other items such as wrapping papers) and retail price net of sales tax	N/A
<b>Health Warnings</b>	Mandatory, must list diseases that have increased risk as a result of smoking	Mandatory, states that vapour may be harmful but does not list diseases	N/A
<b>Outdoor Use Restrictions</b>	Restrictions in specific municipalities	Exempted from restrictions in many municipalities	N/A
<b>Indoor Use Restrictions (cafes, bars, restaurants)</b>	Restricted to dedicated smoking booths in larger establishments. Eating and drinking not allowed	Larger establishments may create dedicated HTP areas where eating and drinking are allowed	N/A

Source: Frost & Sullivan

## Fire safety

HTPs are also recognised as less likely to cause household fires than conventional cigarettes, with conventional cigarettes being the leading cause of household fires in Japan.<sup>49</sup> A recent report convened by the Fire and Disaster Management Agency (FDMA) concluded that the HTPs tested for the report present less risk of causing household fires than conventional cigarettes, and their increased use is likely to lead to a decline in household fires. Furthermore, following the review by its committee, the Tokyo Fire Department announced in August 2019 that the three HTPs tested by the fire safety committee are not considered to be products for "smoking" under the fire regulations in Tokyo and are exempt from the fire regulations due to their low fire risk.

## Electrical device safety standard

With a growing number of HTP devices entering the market, the Japanese Standards Association (JSA) published a Japanese Industrial Standard that establishes standards for the safety of heated tobacco devices (JIS C 9335-2-120: 2020 "Household and similar electrical appliances -Safety- Part2-120: Particular requirements for heated tobacco device"), which is in conjunction with JIS C 9335-1.<sup>50</sup> This standard is expected to safeguard HTP users by setting out requirements for the electrical safety of the products.

<sup>49</sup>Overview of the 2018 White Paper on Fire Service, accessed from <https://www.fdma.go.jp/publication/hakusho/h30/chapter1/section1/para1/38268.html>

<sup>50</sup>Japan Standards Association, accessed from [https://webdesk.jisa.or.jp/books/W11M0090/index/?bunsyo\\_id=JIS+C+9335-2-120%3A2020](https://webdesk.jisa.or.jp/books/W11M0090/index/?bunsyo_id=JIS+C+9335-2-120%3A2020)

## THE LAST WORD

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Evidence from Japan allows some conclusions to be drawn about consumer behaviours when NNTPs become commercially available. These conclusions are likely to apply to other countries, although cultural and social differences between Japan and other countries mean that the Japanese experience may not be directly replicated.

The commercial availability of HTPs in Japan led to a significant drop in conventional cigarette sales, well ahead of the previous rate of decline. Moreover, even after HTPs became available, sales of all tobacco products (HTPs and conventional cigarettes) continued to fall. Although there is mixed evidence, data from the 2019 National Health Survey indicates that 76% of consumers who use HTPs do so exclusively. Only 24% of HTP users maintain dual-use.<sup>51</sup>

The availability of HTPs in Japan has also had minimal impact on initiation or re-initiation among never smokers and former smokers. Only 0.5% of ever tobacco product users had initiated usage through HTPs, and less than 0.1% of former smokers had re-initiated tobacco product use through HTPs.<sup>52</sup> The usage of HTPs by youth is also low.<sup>53</sup>

The Japanese government is differentiating HTPs from conventional cigarettes in regulations, with HTPs generally receiving less-stringent regulatory settings than conventional cigarettes. This supports increased take-up of HTPs by smokers in Japan, which is likely to continue to drive down the consumption of conventional cigarettes.

<sup>51</sup>National Health and Nutrition Survey, 2019, accessed from <https://www.mhlw.go.jp/content/10900000/000687163.pdf>

<sup>52</sup>Langer et al., Tobacco product use after the launch of a heat-not-burn alternative in Japan: results of two cross-sectional surveys, poster presentation, GFN Warsaw, 2019, accessed from [https://www.pmscience.com/resources/docs/default-source/posters2019/langer-2019-tobacco-product-use-after-the-launch-of-a-heat-not-burn-alternative-in-japan.pdf?svrsn=460ed806\\_4](https://www.pmscience.com/resources/docs/default-source/posters2019/langer-2019-tobacco-product-use-after-the-launch-of-a-heat-not-burn-alternative-in-japan.pdf?svrsn=460ed806_4)

<sup>53</sup>Yoneatsu Osaki, Chief investigator, Professor, Division of Environmental and Preventive Medicine, Faculty of Medicine, Tottori University, accessed from <https://mhlw-grants.niph.go.jp/niph/search/NIDD00.do?resrchNum=201709021A>

## ANNEX

### Novel Nicotine and Tobacco Products and Harm Reduction

NNTPs in their current forms have been available for about 15 years, with e-cigarettes first commercially introduced in 2004.<sup>54</sup> The current generation of HTPs was introduced in 2014, and a range of product types and brands have now been launched in countries where they can be legally sold.

HTPs and nicotine-containing e-cigarettes represent the main types of NNTPs currently available, and their main features in comparison with conventional cigarettes are described below.

**Table 2: Comparison of NNTPs and Conventional Cigarettes**

	<b>Conventional Cigarettes</b>	<b>HTPs</b>	<b>e-cigarettes containing nicotine</b>
<b>Description</b>	Products made from leaf tobacco designed for smoking, with or without filters	Products made entirely or partly from leaf tobacco in sticks or pods. They are heated to a level below combustion to generate an inhalable nicotine containing aerosol. Heating source is often, but not always, electronic.	Products contain an e-liquid or salts containing nicotine, which are heated to generate an inhalable nicotine containing aerosol. <small>(Non-nicotine products are also available but are not defined as e-cigarettes in general.)</small>
<b>Source of Nicotine</b>	Naturally occurring in tobacco leaf	Naturally occurring in tobacco leaf	Nicotine added to the liquid or salts
<b>Temperature Range</b>	Typically 800-900°C at lit end	Around or below 350°C, below temperature at which combustion occurs	Variable (roughly 100-250°C)
<b>Formation of Smoke and Ash</b>	Smoke and ash created by combustion of tobacco leaf	No smoke or ash formed, as there is no presence of combustion of tobacco	No smoke or ash formed

Source: Frost & Sullivan

<sup>54</sup>Nguyen et al., Electronic Cigarettes the Past, Present and Future: The History of E-cigarettes, accessed from <https://www.dentalcare.com/en-us/professional-education/ce-courses/ce451/the-history-of-e-cigarettes>

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