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Changes in electronic cigarette use and label awareness among smokers before and after the European Tobacco Products Directive implementation in six European countries: findings from the EUREST-PLUS ITC Europe Surveys

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Background: Article 20 of the European Tobacco Product Directive (TPD), which went into effect in May 2016, regulates electronic cigarettes (e-cigarettes) in the European Union (EU). The aim of this study was to evaluate changes in e-cigarette use, design attributes of the products used and awareness of e-cigarette labelling and packaging among smokers from six EU Member States (MS) before and after TPD implementation. **Methods:** Data come from Wave 1 (2016, pre-TPD) and Wave 2 (2018, post-TPD) of the ITC Six European Country Survey among a sample of smokers and recent quitters who use e-cigarettes from six EU MS. Weighted logistic generalized estimating equations regression models were estimated to test the change in binary outcomes between Waves 1 and 2 using SAS-callable SUDAAN. **Results:** In 2018, current daily/weekly e-cigarette use among adult smokers was just over 2%, but this varied from the highest in Greece (4%) to lowest in Poland (1.2%). From Waves 1 to 2, there was a significant increase in respondents reporting noticing and reading health and product safety information on leaflets inside e-cigarette packaging (8.39–11.62%, $P < 0.001$). There were no significant changes between waves of respondents reporting noticing or reading warning labels on e-cigarette packages/vials. **Conclusions:** e-cigarette use among smokers in these six EU countries is low. Although reported noticing and reading leaflets included in the packaging of e-cigarettes increased significantly from before to after the TPD, there was no significant change in reported noticing and reading of warning labels. Findings indicate the importance of continued monitoring of TPD provisions around e-cigarettes.

Introduction

Across European Union Member States (EU MS), electronic cigarette (e-cigarette) experimentation and current use have risen in recent years, but with wide variability across countries.¹ The percentage of respondents aged 15 years and over from 28 EU MS who reported having tried an e-cigarette at least once, increased from 12% in 2014 to 15% in 2017 although current daily use of e-cigarettes has remained stable at around 2% since 2014.²

Within the EU, e-cigarettes are regulated under Article 20 of the European Tobacco Products Directive (TPD), which aims to ensure smooth functioning of the internal EU market and to harmonize the safety and quality of e-cigarettes.³ In line with the TPD, Commission Implementing Decisions EU 2015/2183 (2015)⁴ and EU 2016/586 (2016),⁵ several e-cigarette design parameters were mandated, including: maximum nicotine concentrations at 20 mg/ml, a maximum volume of 2 ml for refillable e-cigarette tanks, child-resistant refill containers that ensure refill without leakage, the use of a health warning and the inclusion of a leaflet containing instructions for use and information about the addictiveness, the toxicity and contraindications. Additional characteristics of e-cigarettes that are not regulated under the TPD, but which may lead to increased consumer risk due to product mis-use, include the customization of e-cigarette devices by adjusting the voltage or/and the temperature and the possibility of home-mixing e-liquids.^{6,7} This mis-use may be a result of exposure to harmful compounds produced due to the high temperature or voltage or even by illegal substances which can be mixed with the e-liquids.⁶

The inclusion of health warnings and a health and safety leaflet is a potentially efficient way of informing consumers about the possible unwanted risks associated with e-cigarette use and a way of mitigating undesirable events (e.g. leakage during use).⁸ However, prior to implementation of the TPD when there were no policies requiring health warnings and leaflets, noticing health warnings and leaflets in e-cigarettes was low in the EU. As indicated by Wave 1 (2016) of the International Tobacco Control (ITC) Policy Evaluation Project Six European Country (6E) Surveys—before the implementation of the TPD—10.2% of adult smokers who used e-cigarettes reported having ever noticed warning labels, and among them, two-thirds reported having read the warning labels.⁹ Furthermore, reports of noticing leaflets inside packaging of e-cigarettes and reading its content were also low (28.0% noticed and among those who noticed 61.9% read). Similarly, low rates of noticing e-cigarette warning labels were also observed in the ITC Youth Tobacco and e-cigarettes Survey among a sample of youth and young adults (aged 16–19 years, smokers and non-smokers) in the UK, in which 13.5% of respondents reported noticing warning labels during the first months of TPD implementation.¹⁰ In light of the full implementation of Article 20 of the TPD, which went into effect in May 2016 with a transitional compliance period until May 2017, it is important to evaluate the impact of e-cigarette policy provisions and to monitor trends in e-cigarette product preferences. This study therefore aims to evaluate the changes in e-cigarette use, the design attributes of the products used and awareness of e-cigarette labelling and packaging among smokers from six EU MS before and after implementation of the TPD.

Methods

Design

This study was conducted under the European Commission Horizon 2020 funded project *European Regulatory Science on Tobacco: Policy implementation to reduce lung diseases* (EUREST-PLUS), which aims to assess the impact of TPD implementation in Europe.¹¹ Data came from Waves 1 and 2 of the ITC 6E Surveys, a cohort study of adult cigarette smokers (≥ 18 years) from six EU MS: Germany, Greece, Hungary, Poland, Romania

and Spain. Wave 1 (total $n = 6011$) was conducted prior to implementation of the TPD from June to September 2016 and Wave 2 was conducted from February to May 2018 (total $n = 6027$) after the provisions of Article 20 of the TPD were fully implemented.¹² Wave 2 respondents consisted of those respondents followed from Wave 1 (retention rate of 52.9%) who were either current smokers or who were smokers in Wave 1 but who had quit between Waves 1 and 2, as well as a replenishment sample of current smokers to replace those lost to attrition.¹³

A multistage stratified cluster design was used to randomly sample current adult cigarette smokers within geographic strata defined by the Nomenclature of Territorial Units for Statistics regions crossed with degree of urbanization (urban, intermediate and rural). Household addresses were sampled from 100 clusters per country by using a random walk design, with ~ 10 adult smokers enrolled per cluster. Where possible, one female and one male smoker were randomly selected to be interviewed from each household. An information letter was provided to the selected respondents, and consent was also obtained. Face-to-face interviews were conducted by interviewers using tablets (CAPI). Further details about the methodology for the ITC 6E Waves 1 and 2 are described in detail elsewhere.^{14,15}

Measures

Sociodemographic characteristics

Sociodemographic measures were: age (18–24, 25–39, 40–54 and ≥ 55 years), gender (male and female), country, degree of urbanization (urban, intermediate and rural), income level [low ($< \text{€}1750$ for Germany, Greece and Spain, $\leq 150\,000$ Ft for Hungary, ≤ 2000 zł for Poland and ≤ 1000 lei for Romania), moderate ($\text{€}1750$ – 3000 , $150\,001$ – $250\,000$ Ft, 2001 – 4000 zł and 1001 – 2500 lei) and high ($> \text{€}3000$, $> 250\,000$ Ft, $> 4,000$ zł and > 2500 lei) and level of education [low (primary, lower pre-vocational secondary and middle pre-vocational secondary), medium [secondary vocational, senior general secondary and pre-university) and high (higher professional and university bachelor and university masters)].

Use and frequency of e-cigarettes

Lifetime e-cigarette use was assessed with the question ‘Have you ever used an e-cigarette or vaping device, even one time?’ (Yes; No). Frequency of e-cigarette use was assessed among ever users through the question ‘On average, how often do you currently use an e-cigarette/vaping device?’ (Daily; Less than daily, but at least once a week; Less than weekly, but at least once a month; Less than monthly; Not at all). Additionally, ever users were asked, ‘When was the last time you tried or used an e-cigarette/vaping device?’ (< 1 year ago; ≥ 1 year ago); and ‘How many times have you used an e-cigarette or vaping device in your entire life?’ (≤ 2 ; 3–10; 11–99; ≥ 100). We define ‘e-cigarette users’ as smokers who reported any type of current use (daily through less than monthly); however, we define ‘current users’ as those reporting daily or weekly e-cigarette use.¹⁶

Attributes of e-cigarette products

E-cigarette attributes were assessed using the following questions: ‘What type of e-cigarettes is your usual/current brand?’ (Disposable/not refillable; Replaceable prefilled cartridges; Replaceable tank that you fill with liquids); ‘Does the e-cigarette or e-liquid that you currently use/last used contain nicotine?’ (Yes; No; Don’t know), and ‘What flavours of e-cigarette or e-liquid have you used in the last 30 days?’ (Tobacco; Tobacco + menthol; Menthol/mint; Fruit; Candy; Chocolate; Clove; Coffee; Non-alcoholic beverage; Alcoholic beverage; Other; No flavour). Current users who reported using e-cigarettes with nicotine were further asked, ‘What is the nicotine strength of the e-cigarette/cartridge/e-liquid you used last?’ (1–8 mg/ml or 0.1–0.8%; 9–20 mg/ml or 0.9–2.0%; ≥ 21 mg/ml or $\geq 2.5\%$; Don’t know). Additional questions included: ‘Have

you ever mixed different e-liquids?' (Yes; No); 'Can you adjust the power (voltage) or temperature in the e-cigarette or vaping device you currently use most' (No; Yes, but I don't change the settings; Yes, and I change the settings occasionally or regularly).

Noticing and reading e-cigarette health warnings and leaflets

In order to assess awareness of e-cigarette leaflets and health warnings, smokers who used e-cigarettes within the last 30 days were asked the following questions: 'In the past 30 days, have you noticed any health warnings on packaging for e-cigarettes, cartridges or e-liquid bottles or containers?' (Yes; No), and 'As far as you know, is there health and product safety information contained on leaflets inside the packaging of disposable e-cigarettes, cartridges, or e-liquid?' (Yes; No). Respondents who answered 'yes' to noticing warning labels or leaflets, were asked: 'In the last 30 days, have you read any of the health warnings?' and 'have you ever read this information?', respectively (Yes; No).

Statistical analysis

All statistical estimates presented are weighted for sex, age and degree of urbanization. For categorical measures, relative and absolute frequencies were used and for the comparison of proportions, Pearson's chi-squared (χ^2) tests of independence were used. Weighted logistic generalized estimating equations (GEEs) regression models were estimated to test the change in binary outcomes between Waves 1 and 2 using all available respondents in each Wave. GEE models controlled for country, sociodemographic covariates, and smoking status (daily smoker, non-daily smoker or former smoker for Wave 1 smokers who had quit by Wave 2). The statistical analysis was conducted using SAS-callable SUDAAN (SAS Version 9.4, SAS Institute, Cary, NC, USA; SUDAAN Version 11.0.1, Research Triangle Institute, Research Triangle Park, NC, USA) to account for the complex sampling design, survey weights and repeated measures for GEE models.

Results

Sociodemographic characteristics

Supplementary table S1 presents the characteristics of respondents from Waves 1 and 2. In Wave 1, 6011 adult smokers were included, whereas the Wave 2 sample consisted of 6027 respondents, of which 93.4% were smokers and 6.5% recent quitters (those who quit between Waves 1 and 2).

E-cigarette use in Wave 2—after implementation of the TPD

As presented in table 1, at Wave 2, 18.3% of respondents reported using an e-cigarette at least once in their lifetime (ever use), and 4.5% reported having used them more than 100 times. Ever use varied across EU MS, with the highest reported ever use in Greece and Germany (24.4% and 23.2%, respectively) and the lowest in Poland and Hungary (13.9% and 11.7%, respectively; $P < 0.01$). Overall, 1.2% of adult smokers and recent quitters reported daily e-cigarette use, ranging from 2.6% in Greece to 0.5% in Spain ($P < 0.001$).

E-cigarette design attributes in Wave 2—after implementation of the TPD

The majority of e-cigarette users reported using rechargeable e-cigarettes with a tank system (70.9%). The most frequently reported e-liquid flavour was tobacco (41.3%), followed by fruit (33.1%) and candy (12.0%) flavours. Smaller percentages of users also reported using menthol/mint (8.0%), coffee (7.7%), non-alcoholic beverage

(7.5%), tobacco + menthol (6.7%), other flavour (6.2%), chocolate (4.8%), clove (7.7%) and alcohol beverage (3.7%). Differences were observed between countries as presented in detail in table 1. For example, tobacco flavour was most preferable in Poland (58.1%) and least preferable in Spain (22.5%; $P = 0.039$). Also, with regards to menthol/mint flavour use, the highest rate was reported in Denmark (20.2%), whereas in Poland none of the respondents had currently used it ($P = 0.008$).

Overall, 27.6% of e-cigarette users reported currently using e-liquids without nicotine, but this varied by country, with the highest percentage reported in Spain (42.1%) and the lowest in Hungary (12.3%) and Romania (11.8%; $P < 0.05$). Among users, 32.6% reported using e-liquids with nicotine at a strength of 1–8 mg/ml and 25.7% at a strength of 9–20 mg/ml. A small percentage reported using e-liquids with a nicotine strength of 21 mg/ml or greater (2.4%), while 11.7% reported not knowing the nicotine strength of their current/last e-cigarettes.

Approximately one-quarter (24.3%) of users reported having ever mixed their own e-liquids, ranging from 45% in Germany to 6.3% in Spain ($P < 0.001$). Finally, 28.6% of e-cigarette users reported adjusting the settings on their vaping device occasionally or regularly, with Germany having the highest percentage (44.6%) and Spain the lowest (11.3%; $P < 0.01$).

Overall, 3.8% of respondents reported having noticed warning labels in the past 30 days, among which 50.1% read them. Additionally, 11.6% of respondents reported noticing leaflets inside the packaging, with 34.7% having ever read the contained information.

Differences of e-cigarette use, attributes of product used and label awareness pre- and post-TPD implementation

Table 2 presents changes in e-cigarette use across the total samples in both Wave 1 (pre-TPD) and Wave 2 (post-TPD) among all six EU MS. From Waves 1 to 2, there was no significant change in the proportion of respondents who reported current (daily or weekly) e-cigarette use, nor in those who reported use of flavoured e-liquids (including tobacco flavour), using nicotine-containing e-liquids, or ever mixing e-liquids. However, there was a significant increase in respondents reporting noticing that there is health and product safety information contained on leaflets inside e-cigarette packaging (8.4–11.6%, $P < 0.001$). Furthermore, among those who noticed leaflets in the packaging, there was a significant increase in those who reported reading the information contained in the leaflets (2.8–3.9%, $P < 0.05$). There was also a small increase in the percentage of respondents reporting the ability to adjust the settings on their vaping device (1.2–1.8%, $P < 0.05$). Finally, no significant changes were found between waves of respondents reporting noticing or reading warning labels on e-cigarette packages/vials.

Discussion

This study presents new population-based data on e-cigarette use, their design attributes and the noticing and reading of warning labels and leaflets within the packaging of e-cigarettes after the full implementation of TPD Article 20. Among adult smokers and recent quitters (those who quit between the two study waves) from six EU MS, current daily/weekly use of e-cigarettes remained stable from 2016 to 2018. In 2018, current use of adult smokers and recent quitters was just over 2%, but this varied from 2.6% in Greece to 0.5% in Spain. This prevalence compares to findings from the 2017 Special Eurobarometer, in which the percentage of daily and weekly e-cigarette use across the general adult population (smokers and non-smokers) in 28 EU MS was 1.8%, but with variation across MS.²

We found that after implementation of the TPD there was an increase in consumers reporting awareness of the inclusion of

Table 1 E-cigarette frequency of use and product attributes by country among current and former smokers in six EU countries (Wave 2, weighed)

	DE		GR		HU		PL		RO		ES		ALL		P
	%	(n)	%	(n)	%	(n)	%	(n)	%	(n)	%	(n)	%	(n)	
Total sample of Wave 2 (n = 6027)															
Frequency of use															
Lifetime e-cigarette use															
Never	76.9	774	75.6	744	88.2	881	86.2	837	81.1	824	82.4	827	81.7	4887	<0.001
2 or fewer times	7.4	74	5.6	63	5.6	55	2.7	29	9.7	90	7.4	65	6.4	376	
3–10 times	5.9	57	3.4	33	2.4	25	3.5	34	2.6	27	3.5	44	3.6	220	
11–99 times	5.7	52	4.6	50	2.2	20	3.4	34	3.2	28	3.7	45	3.8	229	
100+ times	4.2	45	10.8	92	1.5	15	4.3	41	3.4	31	3.0	27	4.5	251	
E-cigarette use frequency															
Daily ^a	1.8	18	2.6	28	0.7	7	0.9	8	0.7	8	0.5	7	1.2	76	<0.001
Weekly	1.5	15	1.4	14	0.8	7	0.3	3	0.8	8	1.8	14	1.1	61	
Monthly	2.1	17	0.7	6	0.6	5	0.3	2	0.4	3	0.2	3	0.7	36	
<Monthly	1.2	14	0.5	5	0.8	9	0.3	3	1.3	13	2.4	14	1.1	58	
Non-user ^b	93.4	938	94.8	929	97.1	968	98.3	956	96.8	967	95.2	970	95.9	5728	
E-cigarette product attributes ^c															
What type of e-cigarette is usual/current brand															
Disposable (non-refillable, non-rechargeable)	2.6	2	1.0	1	31.0	8	4.2	1	12.2	3	26.3	8	11.8	23	0.109
Rechargeable (pre-filled cartridges)	26.2	18	12.8	7	19.7	5	14.9	2	17.8	8	8.6	6	17.3	46	
Rechargeable (tank system)	71.2	44	86.2	44	49.3	15	81.0	12	70.0	16	65.1	24	70.9	155	
Flavour used in last 30 days															
No flavour	92.9	59	75.1	40	91.2	25	92.1	15	88.8	29	83.1	32	86.4	200	0.292
Tobacco	44.9	26	56.4	31	38.2	10	58.1	9	32.1	12	22.5	13	41.3	101	
Tobacco + menthol	8.7	6	1.7	1	5.4	1	20.0	3	3.4	1	7.4	4	6.7	16	0.323
Menthol/mint	20.2	12	2.9	2	4.9	1	0.0	0	9.1	2	0.3	1	8.0	18	0.008
Fruit	57.5	33	21.0	12	36.2	10	34.9	7	19.4	5	18.8	11	33.1	78	0.009
Candy	17.2	11	18.3	9	0.0	0	18.6	4	7.1	2	6.6	5	12.0	31	0.006
Chocolate	12.5	8	3.5	2	0.0	0	3.0	1	3.4	1	0.0	0	4.8	12	0.046
Clove	6.8	4	3.6	2	7.7	2	0.0	0	4.9	2	0.0	0	4.2	10	0.139
Coffee	13.7	10	10.2	6	0.0	0	9.4	1	3.4	1	3.5	2	7.7	20	0.021
Non-alcoholic beverage	16.4	9	3.5	2	0.0	0	4.1	1	12.8	3	1.7	1	7.5	16	0.029
Alcoholic beverage	6.9	4	1.7	1	2.6	1	9.4	1	3.4	1	0.0	0	3.7	8	0.290
Other	14.2	8	3.6	2	0.0	0	3.0	1	7.1	2	2.0	2	6.2	15	0.043
Nicotine strength of current/last e-liquid															
No nicotine	28.7	12	30.1	13	12.3	3	32.1	4	11.8	3	42.1	9	27.6	44	0.015
1–8 mg/ml (0.1–0.8%)	38.0	21	31.9	15	22.4	5	18.9	3	41.4	6	30.5	4	32.6	54	
9–20 mg/ml (0.9–2.0%)	25.5	13	31.1	16	31.5	5	45.4	5	15.4	3	7.3	3	25.7	45	
≥21 mg/ml (2.1% or more)	2.9	1	5.6	3	0.0	0	0.0	0	0.0	0	0.0	0	2.4	4	
Not reported	4.8	3	1.3	1	33.8	5	3.6	1	31.4	6	20.1	6	11.7	22	
Ever mixed e-liquids															
Yes	40.5	18	30.5	11	16.3	2	25.0	2	15.0	2	1.0	1	24.3	36	<0.001
No	53.8	22	62.6	30	68.7	10	50.2	7	33.1	6	38.0	15	51.6	90	
Not reported	5.7	4	6.9	3	15.0	3	24.9	3	51.9	8	61.0	8	24.0	29	
Can adjust settings on vaping device															
No	18.4	12	18.6	10	25.0	6	37.0	6	16.4	6	8.6	6	18.4	46	0.001
Not reported	16.7	12	9.0	5	28.9	5	21.0	3	50.0	12	55.7	11	27.0	48	
Yes, but you don't change it	20.3	14	47.2	22	15.3	3	15.6	3	15.2	3	24.5	5	26.0	50	
Yes, and you change the settings occasionally	30.2	16	23.5	13	23.0	5	8.7	1	18.5	3	9.4	6	21.5	44	
Yes, and you regularly adjust the settings	14.4	8	1.8	1	7.8	1	17.7	1	0.0	0	1.9	2	7.1	13	
Warning labels															
Noticed warning labels in past 30 days	2.9	23	2.5	22	2.9	20	3.7	20	6.5	48	4.3	29	3.8	162	0.084
Read warning labels in past 30 days ^a	40.1	9	71.9	16	67.2	14	64.1	12	39.8	22	38.2	9	50.1	82	
Leaflets															
Noticed leaflets inside packaging	14.1	105	21.7	180	12.2	84	8.5	48	8.6	57	4.3	35	11.6	509	<0.001
Ever read information on leaflets ^d	22.1	20	51.3	87	9.1	10	40.6	19	41.1	23	34.2	9	34.7	168	<0.001

a: Among those who noticed warning labels.

b: Both never e-cigarette users and e-cigarette quitters are included.

c: Sample: daily/weekly/monthly/less than monthly e-cigarette users (n = 231).

d: Among those who noticed leaflets.

leaflets in e-cigarette packaging and reading the information contained in these leaflets. This parallels findings by Girvalaki *et al.*,¹⁷ in which a prospective assessment of compliance of e-cigarettes from nine EU MS (including the six countries in this study) found an increase in the inclusion of a leaflet from before TPD implementation (26.2%) to after (53.3%, $P < 0.001$). Both the information included in a leaflet and its design have been found to have a positive impact in providing information to consumers, and as shown in these two studies, one of the factors that has possibly contributed to the increase of the proportion of people who notice and read the

leaflets could be the increase on e-cigarette products which have them. Interestingly, there was no significant change in noticing and reading warning labels before vs. after TPD implementation among e-cigarette users. Although Girvalaki *et al.* found an increase in compliance of the inclusion of health warnings on e-cigarette vial, box or leaflet (32.7% pre-TD to 86.0% post-TPD, $P < 0.001$), it is important to note that the most common placing of a health warning was on the box (72.0% post-TPD) and lowest for placement on the actual refill vials (32.7%). It is therefore plausible that the low rates of noticing health warnings may be due to the fact that

Table 2 Differences between the pre- and post-TPD waves in e-cigarette use, e-cigarette attributes and reading and noticing warning labels and health warning leaflets among current e-cigarette smokers/quitters^a

Outcomes	Wave 1		Wave 2		p ^b
	%	95% CI	%	95% CI	
Current daily/weekly e-cigarette user vs. otherwise ^c	1.66	1.28–2.15	2.17	1.74–2.71	0.105
Used flavoured e-liquid in last 30 days ^c	0.86	0.61–1.22	1.29	0.98–1.68	0.071
Used a nicotine containing e-liquid ^d	1.46	1.09–1.97	1.70	1.36–2.14	0.412
Ever mixed e-liquids ^c	0.48	0.30–0.78	0.57	0.40–0.81	0.586
Can adjust device settings ^c	1.16	0.86–1.57	1.77	1.41–2.22	0.017
Noticed warning labels on e-cigarette packs/vials ^e	3.31	2.50–4.37	3.83	3.06–4.78	0.397
Read warning labels on e-cigarette packs/vials ^e	1.75	1.22–2.50	1.96	1.42–2.71	0.637
Noticed leaflets in packaging ^f	8.39	7.11–9.88	11.62	10.23–13.17	<0.001
Read information in leaflets ^f	2.77	2.18–3.51	3.97	3.23–4.86	0.015

a: Logistic regression models estimated using GEE and all respondents present in either Waves 1 and/or 2. GEE models controlled for sex, age group, country, residence (urban/intermediate/rural), income, education and smoking status [daily/non-daily or quitter (at Wave 2)].

b: For differences between Waves 1 and 2.

c: Among current smokers/quitters, Wave 1 (n) = 5897/Wave 2 (n) = 5939.

d: Among current smokers/quitters, Wave 1 (n) = 5830/Wave 2 (n) = 5877.

e: Among current smokers/quitters who were aware of e-cigarettes, Wave 1 (n) = 4227/Wave 2 (n) = 4316.

f: Among current smokers/quitters who were aware of e-cigarettes, Wave 1 (n) = 4231/Wave 2 (n) = 4312.

consumers possibly discard the external packaging and retain only the e-liquid vial. Findings are also consistent with another study using ITC data which found that the majority of respondents reported not noticing or reading e-cigarette health warning labels on outside packaging or leaflet inserts during transitional implementation of TPD Article 20 in 2016.¹⁸ In that study, respondents in the UK were also not more likely to report noticing warning labels compared with respondents in Australia, Canada and the USA where warnings were not mandatory at the time of this study.¹⁸

Preference in e-cigarette attributes in Wave 2 remained similar to findings from Wave 1,⁹ regarding flavoured e-liquids, nicotine contamination and tank style, with no significant changes. Our findings regarding the use of flavoured e-liquids are consistent with other studies reporting that e-cigarette adult users prefer flavoured e-liquids with tobacco and fruit ranking among the top flavours.¹⁹ We also did not find an increase in percentage of users ever mixing e-liquids from Waves 1 to 2. However, there are significant cross-country differences, with a significantly greater percentage of German respondents reporting ever mixing e-liquids compared with the other countries. We did however find a significant increase in the percentage of users reporting adjusting the device settings on their e-cigarette, including the power (voltage) or temperature from Waves 1 to 2. Approximately one in four users reported regularly or occasionally adjusting these settings in Wave 2; this practice was most common among German respondents and varied across countries. Recent studies indicate that the customization of e-cigarette attributes may increase exposure to unwanted vapour components created due to product misuse, which may potentially lead to adverse health effects.²⁰

Strengths and limitations

Our study used a solid design with the questionnaire and sampling methodology were consistent across countries, enabling cross-country comparisons. However, there are limitations of this study that must be considered when interpreting results. First, our sample only included cigarette smokers who also reported e-cigarette use (dual users), precluding the group of exclusive e-cigarette users which may have different characteristics and attitudes and therefore, the results may not be generalizable to exclusive e-cigarette users. In addition, although the samples of both Waves (1 and 2) consisted of ~6000 respondents, the prevalence of e-cigarette use was low. The small sample size limited the number of variables that could be assessed during the analyses. Also, the quantitative approach which we used only provides limited information on consumers'

behaviours, while a qualitative study could give a more in depth understanding. Finally, the data were self-reported by the participants and as such, they may be subject to misclassification bias, while reporting bias could also exist as respondents had to recall information. Despite the above the current study provides important data regarding the product parameters and user characteristics of e-cigarettes across 6 EU MS. As the results of this study are representative only for the six EU MS included and in order to have a better understanding of the impact of TPD on e-cigarette users' behaviours, more detailed studies evaluating the differences before and after TPD should be conducted in more European countries. Finally, future research should examine whether the content and positioning of warning labels on e-cigarettes are effective at conveying accurate information to consumers.

Conclusion

This study presents recent estimates on e-cigarette use and characteristics of e-cigarette attributes after the full implementation of TPD among a sample of adult smokers and recent quitters from six EU MS. We found that the overall e-cigarette uses in the six EU MS remained stable in this sample from 2016 to 2018. Although reported noticing and reading leaflets included in the packaging of e-cigarettes increased significantly from before to after the TPD, there was no significant change in reported noticing and reading of warning labels. Continued monitoring of EU trends in e-cigarette use and product attribute preferences, and evaluation of the impact of TPD Article 20, are important components to comprehensive regulation of tobacco and tobacco-related products.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Key points

- Article 20 of the European Tobacco Product Directive (TPD), which went into effect in May 2016, regulates the safety and quality of electronic cigarettes (e-cigarettes) in the European Union.
- After the TPD there was a significant increase in the percentage of users reporting the ability to adjust the device settings on their e-cigarette, including the power (voltage) or temperature.
- Reported noticing and reading leaflets included in the packaging of e-cigarettes increased significantly from before vs. after the TPD.
- There was no significant change in reported noticing and reading of warning labels before vs. after the TPD.

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