

„E-cigarettes from the perspective of a health regulator“



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1. INTRODUCTION AND STATISTICS

1. Introduction and statistics

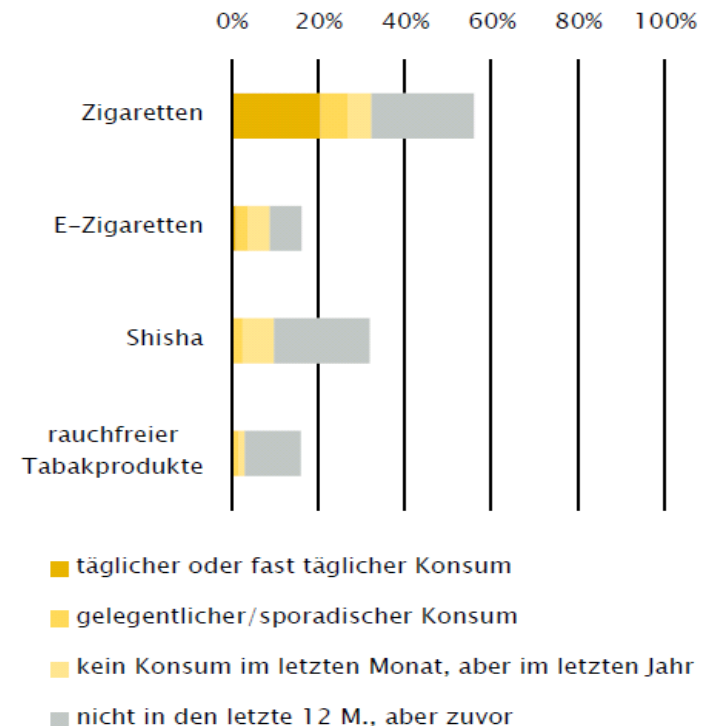
Smoking prevalence of smoking products with nicotine in

Austria:

- about 27 % of austrians smoke cigarettes almost every day
- about 5 % of austrians smoke **e-cigarettes** almost every day
- about 18% of austrians have already smoked an e-cigarette in their life

(General Population Survey/GPS 2015, Gesundheit Österreich GmbH/BMG 2016, veröffentlicht 2016)

Prävalenzen nikotinhaltiger Produkte



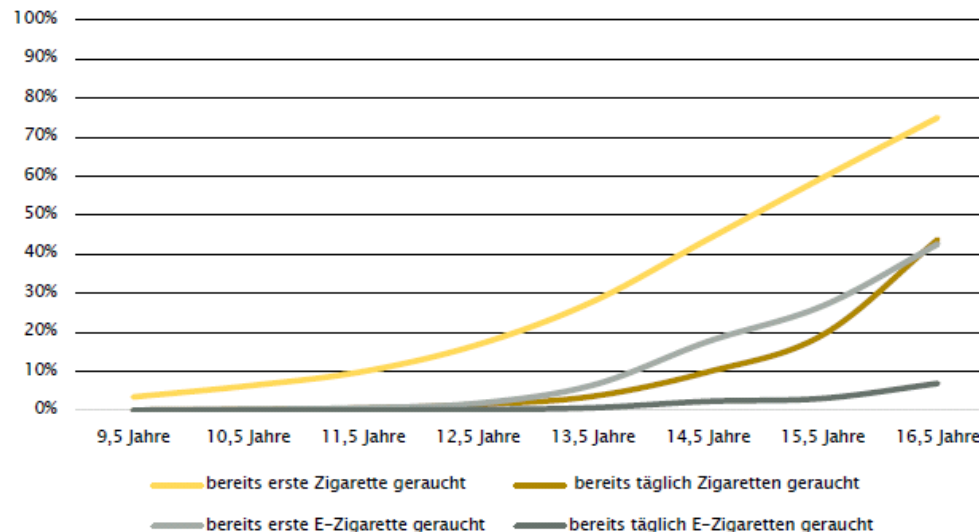
1. Introduction and statistics



Starting age of smoking cigarettes and e-cigarettes:

- **cigarettes:** **50%** of 15-years-olds have already smoked a cigarette in their life, **15%** of them even smoke cigarettes daily
- **e-cigarettes:** about **20%** of 15-years-olds already have smoked an e-cigarette in their life, about **2%** of them smoke e-cigarettes daily

Verlaufskurve des Einstiegsalters bei Zigaretten und E-Zigaretten



1. Introduction and statistics



Effects on health:

- e-cigarettes are **less harmful** than conventional cigarettes
- but **amount of risk reduction** still unknown
- **vaped aerosol** causes eye and respiratory irritation
- effects of **vaped aromas** still unknown
- **nicotine** can lead to cardiovascular diseases, diabetes or cancer
- **formaldehyde, small particles, acetaldehyde and metals** cause cancer
- **Summary**: For smokers e-cigarettes are less harmful than conventional cigarettes, but for non-smokers (especially for minors) they are an avoidable health risk!

1. Introduction and statistics

Smoking cessation:

- “harm reduction”?
- **long-term** use of e-cigarettes can be harmful
- lack of long-term surveys/data
- no evidence based results if e-cigarettes really lead to **cessation**
- **other alternatives:** nicotine patches, nasal spray, etc.
- 70% of smokers use **cigarettes and e-cigarettes (“dual use”)** → health risk even higher
- **reduction of motivation** to stop smoking

1. Introduction and statistics



Youth protection:

- life-style product
- e-cigarette users and smokers share **similar social and behavioural characteristics**
- development of **lungs** not finished yet
- **Poland**: 16% of 16-18 years old smokers used e-cigarettes before starting to smoke conventional cigarettes
- **France**: 11,6% of smoking minors used e-cigarettes before starting to smoke conventional cigarettes
- **specific effect** of e-cigarettes on minors still unknown



1. Introduction and statistics

Market research:

- almost all e-cigarettes users **also smoke tobacco or used to do so**
- **3 main reasons** for using e-cigarettes:
 - **less harmful** for smokers
 - **cheaper** than tobacco
 - They are expected to **help the user stop smoking**
- only **8% use nicotine-free liquid**
- **tobacco flavour** is by far the most popular flavour, followed by menthol
- The great majority of current vapers **intend to go on using e-cigarettes.**
- the health risks are **strongly dependent on individual vaping and smoking habits**





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2. WHO/FCTC



FCTC

WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL



WHO Framework Convention on Tobacco Control (FCTC):

- first global public health treaty
- currently **180 parties**
- Austria ratified the FCTC in **Sept. 2005**
- at that time **no explicit regulations regarding e-cigarettes**
- **Conference of Parties (COP)** → governing body of the FCTC and represents the Parties of the Convention
- decisions concerning e-cigarettes in **COP 6** (Moscow, Oct. 2014) und **COP 7** (Neu Dehli, Nov. 2016)



- **(technical) Report by WHO** (July 2014, FCTC/COP/6/10) about electronic nicotine delivery systems (ENDS):
 - recommendations by the **WHO Study Group on Tobacco Product Regulation** (TobReg) and analysis from a **WHO survey** on tobacco products
 - **use of ENDS doubled** among both adults and adolescents from 2008 to 2012
 - ENDS aerosol is **not only “water vapour”**, but it also poses serious threats to humans (e.g. eye and respiratory irritation)
 - less toxic for the smokers than conventional cigarettes, but the **amount of risk reduction is still unknown**

2.1. COP 6, Oct. 2014/Moscow



- the efficacy in **helping smokers to quit smoking** has not been systematically evaluated yet
- once addicted to nicotine through ENDS people will **switch to cigarette smoking**
- ENDS created challenges to the **core message of tobacco control** (“tobacco use should not be started and if started it should be stopped”)
- The use of ENDS in places where smoking is banned will make **enforcing smoke-free policies more difficult**
- **Marketing activities** have the potential to glamorize smoking and attracting children/minors and non-smokers.



- **Decision** about electronic nicotine delivery systems and electronic non-nicotine delivery systems (18th October 2014): Goals are to
 - **prevent the initiation** of ENDS/ENNDS by non-smokers and youth
 - **minimize health risks** to ENDS/ENNDS users and protect non-users from exposure
 - prevent unproven **health claims**
 - **prohibit or regulate** ENDS/ENNDS
 - ban or restrict **advertising and sponsorship**
 - **monitoring** of ENDS/ENNDS use



- **(technical) Report by WHO** (August 2016, FCTC/COP/7/11) about ENDS/ENNDS:
 - still unknown whether e-cigarettes can really lead to **cessation of smoking**
 - levels of toxicants can **vary enormously** and sometimes reach even **higher levels than tobacco smoke**
 - **flavour** is one of several reasons that influences people's willingness to try e-cigarettes
 - most flavours in e-cigarettes pose **health risks** from long-term use, especially the sweet ones
 - particles, metals and nicotine can adverse health effects for **bystanders**
 - the use by **minors** who have never smoked at least doubles their chance of starting to smoke



- **Decision** about ENNDS (12th November 2016):
 - the **report** of November 2016 has to be considered
 - **prohibition** or at least **restriction** of ENNDS is encouraged
 - **monitoring** and **reporting** on scientific, regulatory and market developments are requested





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**3. TPD II 2014/40/EU
(IMPLEMENTED IN NATIONAL
LAW/TNRSG
SINCE MAY 21ST 2016)**



3. TPD II



- **DIRECTIVE 2014/40/EU** on the approximation of the laws, regulations and administrative provisions of the EU-Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC → **TPD II**
- **aims of the revision:**
 - smooth functioning of the internal market
 - high level of health protection



- **reasons for the revision** (Directive 2001/37/EC):
 - new **scientific data**, e.g. concerning flavouring tobacco and health warnings
 - **novel products** on the market (e.g. e-cigarettes)
 - **substantial differences** between the national laws in the MS
 - mandatory measures of the **FCTC** have to be implemented
 - **health risks** (every year about 15.500 people die because of smoking, WHO Global Report on the Tobacco Attributable Mortality, 2004, veröffentlicht 2011)

3. TPD II



- definition of „e-cigarettes“ in **Art. 2 paragraph 16 TPD II**:
 - “electronic cigarette” means a product that **can** be used for **consumption of nicotine-containing vapour via a mouth piece**,
 - or **any component of that product**, including a cartridge, a tank and the device without cartridge or tank.
 - Electronic cigarettes can be **disposable or refillable** by means of a refill container and a tank, or rechargeable with single use cartridges.
- only regulations for e-cigarettes **with nicotine**
- no **age limit for electronic cigarettes** or refill containers, but in **recital 48** the MS are encouraged to regulate it

3. TPD II



- **COMMISSION IMPLEMENTING DECISION 2016/586** of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes – **possible health risks***:
 - **poisoning** from ingesting e-liquids containing nicotine (especially for young children)
 - **skin reactions** related to dermal contact with e-liquids containing nicotine and other skin irritants
 - risks associated with **home blending** and
 - risks due to using **untested combinations of e-liquid and device or hardware customization**
- EC is empowered to adopt **additional delegated/implementing acts** concerning e-cigarettes (e.g. Art. 20 paragraph 11 TPD II)



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4. TOBACCO LAW IN AUSTRIA



4.1. Tobacco Law in Austria - background



- The principle version of Tobacco Law was implemented in 1995 (**TabakG, BGBl. Nr. 431/1995**)
- **change of paradigm 2005** → non-smoking is the general rule and smoking is the exception
- many amendments especially **since 2009** (e.g. smoking ban in public places, sanctions for the violation of Tobacco Law, partial smoking ban in restaurants, bars, etc.)
- The TPD II was implemented in national law with May 21st 2016 by the **TNRSG, BGBl. I Nr. 22/2016** (Tobacco and Non-smoker Protection Law).

4.2. E-cigarettes in Austria



- in **§ 1 (1b) TNRSG** same definition/e-cigarettes like in TPD II
- **nicotine-free** e-cigarettes are also included
(**Recommendation/Expert Group/BMGF** from 8th June 2015)
- **§ 10b TNRSG** - notification 6 months before taking place on the market:
 - name and contact details of the manufacturers,
 - list of all ingredients,
 - information on the nicotine doses,
 - description of the production process, etc.
- **§ 10c TNRSG** – labelling, packaging (e.g. health warnings) and leaflet with information



4.2. E-cigarettes in Austria



- **§ 10d TNRS** – control and measures:
 - notification of sales volume
 - information about the different ways of sale
 - summary of all available market surveys
 - **possible measures:** temporary ban on placing on the market, requisition or forfeiture
- regulations regarding **advertising/sponsorship** and **smoking bans** in schools, public places, restaurants, bars, etc. also **include e-cigarettes (with and without nicotine!)** since the amendment of August 2015 (BGBl. I Nr. 101/2015)
- **Outlook:**
 - total **smoking ban in restaurants, bars**, etc. in **May 2018** and
 - raising the minimum age for smoking to **18 years in the middle of 2018** (decision of the federal states conference/March 2017)

4.3. VfGH G 164/2016



- **decision by the Constitutional Court (G 164/2016), 14th March 2017**
- **Claimant:** importer of e-cigarettes and refill containers
- **Requests:** repeal of
 - **legal inclusion** of e-cigarettes (with and without nicotine), refill container and liquids (§ 1 Z 1b, § 1 Z 1c und § 1 Z 1I TNRSG),
 - **ban on distance sales** of e-cigarettes (§ 2a, § 1 Z 1e TNRSG),
 - information about the **different ways of sale** (§ 10d Abs. 1 Z 3 TNRSG),
 - summary of all available **market surveys** (§ 10d Abs. 1 Z 4 TNRSG)
 - the establishment of a **new system for information** about all health effects of e-cigarettes (§ 10d Abs. 3 TNRSG)

Decision by the Constitutional Court: Confirms

- rejection in all health and youth policy points!
- political sphere of jurisdiction regarding the inclusion of **nicotine-free** e-cigarettes
- ban of **distance sale**:
 - **health objectives** (especially for consumers and minors) have more weight than the restrictions of manufacturers rights
 - distance sale **between traders are still allowed**

4.3. VfGH G 164/2016



- **equal treatment** of cigarettes and e-cigarettes:
 - also **effects on health** and **addiction potential**
 - specific **health effects still unknown**
 - special **appeal/attractiveness** for non-smokers
- information about the **kind of sales** and **market surveys** important for science



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5. Controversial discussions regarding advantages and harm of e-cigarettes



Public Health England's (PHE)	The Lancet (world's leading independent general medical journal)/29 th August 2015	DKFZ (German Cancer Research Centre)
<p>“E-cigarettes are around 95% safer than smoking” (19th August 2015)</p>	<p>“There was a lack of hard evidence for the harms of most products on most of the criteria.”</p>	<p>Lack of evidence concerning smoking cessation (often “dual use”) harm reduction</p>
	<p>“There was no formal criterion for the recruitment of the experts.”</p>	<p>long-term effects still unknown</p>
	<p>“There is a potential conflict of interests.”</p>	<p>entry product for non-smokers</p>

6. The perspective of a health regulator



- **dynamic development of a new product**
- **Focus/health policy:**
 - health protection
 - smoking cessation
 - youth protection
 - non-smoker/-vapor protection
- new challenges for the health and youth policy regarding the **attractiveness, toxicity and addiction**
- protection against **exposure**
- at that moment **harmlessness** of (nicotine-free) e-cigarettes **not proven**
- regulations concerning **ban on vaping** necessary!
- **monitoring** of the different types of e-cigarettes (demand for regulations!)
- The health policy should guarantee **preventive solutions**: TPD II, TNRSKG, etc.
- confirmation by Constitutional Court (**VfGH G 164/2016**)

7. Conclusion



- The consumption of e-cigarettes are **increasing** each year
- amount of risk reduction still **unknown**
- **complete smoking cessation** should be the rule!
- **core message of tobacco control** (WHO/FCTC): *“Tobacco use should not be started and if started it should be stopped!”*
- demand for regulations concerning the harmonization of the market on EU and national level
- **equal treatment** of cigarettes and e-cigarettes (with and without nicotine) in Austria (justified by Constitutional Court, G 164/2016!)
- **legal development** depends on the results/studies regarding the health risks of e-cigarettes
- **challenge/health policy demands** focusing on health protection, smoking cessation, youth protection and non-smoker/-vapor protection



Thank you very much for your attention!