

# HØRINGSSVAR

Udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Maj 2016

# E-cigaretter

## Høringssvar uden bemærkninger

Aalborg Universitet

Danmarks Apotekerforening

Danmarks Vejlederforening

Dansk Erhverv

Dansk Selskab for Distriktpsychiatri

Dansk Selskab for Folkesundhed

Danske Erhvervsskoler

Forbrugerombudsmanden

Landselevbestyrelserne for Social- og Sundhedsuddannelsen og for Pædagogisk  
Assistent-uddannelsen

LOS – De private sociale tilbud

Rigsrevisionen

SDU

Søfartens Ledere

Maj 2016

**From:** Bodil Brander Christensen  
**Sent:** 27 Apr 2016 07:52:35 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Cc:** ADM Teknat/Sund fakultetskontor  
**Subject:** VS: Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. (615-10-00001). AAU svar

Sikkerhedsstyrelsen, Erhvervs- og Vækstministeriet  
Att: Branka Klisura

Kære Branka Klisura

Aalborg Universitet har ingen kommentarer til udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Venlig hilsen

Bodil



**AALBORG UNIVERSITET**  
**Bodil Brander Christensen**  
Sekretariatschef | Ledelsessekretariatet  
Det Sundhedsvidenskabelige Fakultet

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Aalborg Universitet | Niels Jernes Vej 10 | 9220 Aalborg Øst |

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**Fra:** Majken Toft Larsen [<mailto:MTL@sik.dk>]

**Sendt:** 7. april 2016 13:51

**Til:** Majken Toft Larsen

**Emne:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Hermed sendes udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. i høring.

Venlig hilsen



**Majken Toft Larsen**  
Jurist, fuldmægtig

E-mail: [MTL@sik.dk](mailto:MTL@sik.dk)

Sikkerhedsstyrelsen  
Nørregade 63  
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Tlf.: 33 73 20 00  
[www.sik.dk](http://www.sik.dk)

*Denne e-mail og enhver vedhæftet fil er fortrolig og alene tiltænkt modtageren. Såfremt De ikke er rette modtager, vil adgang til e-mailen være ubeføjet, og enhver udnyttelse eller videregivelse af e-mailens indhold være uretmæssig og potentielt i strid med lovgivningen. Såfremt De ikke er rette modtager, bedes De venligst omgående underrette os og derefter slette e-mailen og enhver vedhæftet fil. På forhånd tak.*



**Danmarks Apotekerforening**

Bredgade 54 · 1260 København K

Telefon 33 76 76 00 · Fax 33 76 76 99

apotekerforeningen@apotekerforeningen.dk · www.apotekerforeningen.dk

**apotek**

Sikkerhedsstyrelsen  
Nørregade 63  
6700 Esbjerg

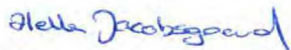
06-05-2016

HJ/4201/00001

Danmarks Apotekerforening har modtaget udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldelsesbeholdere mv. jf. journalnr. 615-10-00001 i høring.

Det skal hermed meddeles, at foreningen ikke har bemærkninger til det fremsendte udkast.

Med venlig hilsen



Helle Jacobsgaard

**Til:** Sikkerhedsstyrelsen

**Fra:** Danmarks Vejlederforening

08-04-2016

**Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.**

Danmarks Vejlederforening (DVF) takker for muligheden for at afgive høringssvar.

DVF har intet at bemærke.

På vegne af Danmarks Vejlederforenings bestyrelse

**Charlotte Knagh Trojahn**

Formand for Danmarks Vejlederforening

[www.vejlederen.org](http://www.vejlederen.org)

[formand@danmarksvejlederforening.dk](mailto:formand@danmarksvejlederforening.dk)

Tlf. 42461501

**From:** Henrik Lundgaard Sedenmark  
**Sent:** 4 May 2016 08:14:46 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Cc:** Søren Büchmann Petersen; Lotte Engbæk Larsen; Lotte Holmstrup  
**Subject:** Høringssvar vedr. indberetning af tobaksvarer mv. og høringssvar vedr. anmeldelse af elektroniske cigaretter mv (j.nr. 615-20-00001 og 615-10-00001)

Vedhæftet finder I Dansk Erhvervs høringssvar vedr. udkast til følgende to bekendtgørelser:

- udkast til bekendtgørelse om indberetning af tobaksvarer og urtebaserede rygeprodukter, samt anmeldelse af nye kategorier af tobaksvarer mv.
- udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Vedhæftet er tillige vores tidligere høringssvar af 22. januar 2016, som vi ikke kan se har været medtaget ved overdragelsen til Folketinget.

Måtte der være spørgsmål, er I velkomne til at kontakte os.

Med venlig hilsen

Henrik Lundgaard Sedenmark  
Chefkonsulent

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DIREKTE: +45 3374 6597  
[HLS@DANSKERHVERV.DK](mailto:HLS@DANSKERHVERV.DK)



Dansk Erhverv er erhvervsorganisation og arbejdsgiverforening for fremtidens erhverv. Vi repræsenterer 17.000 virksomheder og 100 brancheorganisationer inden for handel, rådgivning, oplevelse, transport og service.

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DANSK ERHVERVS  
ÅRSDAG 2016

LÆS MERE OG TILMELD DIG HER »

DIS  
RUP  
TION  
DK



Nye forretningsmodeller

Sikkerhedsstyrelsen  
Att.: Branka Klisura  
Nørregade 63  
6700 Esbjerg

sik@sik.dk

4. maj 2016

## **Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.**

Dansk Erhverv har den 7. april 2016 modtaget høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Dansk Erhverv har ikke bemærkninger til bekendtgørelsen, men skal i det hele henvise til de høringssvar, vi har afgivet den 17. marts 2015, samt 19. og 22. januar 2016 vedrørende lov om fremstilling, præsentation og salg af elektroniske cigaretter mv. Vi skal den forbindelse bemærke, at vores ændrede høringssvar af 22. januar 2016 ikke synes at være kommet med i de samlede høringssvar, hvorfor vi fremsender svaret på ny.

Med venlig hilsen

**Henrik Lundgaard Sedenmark**  
Chefkonsulent

HLS  
hls@danskerhverv.dk

Side 1/1

-  
Deres ref.: 615-10-00001  
Vores ref.: 2016-00424

**From:** Lotte Engbæk Larsen  
**Sent:** 28 Jan 2016 15:00:08 +0000  
**To:** Henrik Lundgaard Sedenmark  
**Subject:** VS: Høring vedrørende forslag til lov om elektroniske cigaretter m.v.  
**Attachments:** HØR Ændring udkast til lovforslag om regulering af elektroniske cigaretter og genopfyldningsbeholdere.pdf

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**Fra:** Lotte Engbæk Larsen  
**Sendt:** 22. januar 2016 13:17  
**Til:** 'primsund@sum.dk' <primsund@sum.dk>; 'pkh@sum.dk' <pkh@sum.dk>  
**Cc:** Lotte Holmstrup <lho@danskerhverv.dk>; Jeanette Rohd Gernsøe <jrp@danskerhverv.dk>  
**Emne:** SV: Høring vedrørende forslag til lov om elektroniske cigaretter m.v.

Kære Patrick.

Som aftalt fremsender hermed en ændring af Dansk Erhvervs høringssvar vedr. vedrørende forslag til lov om elektroniske cigaretter m.v..

Mvh  
Lotte

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**Fra:** Lotte Engbæk Larsen  
**Sendt:** 19. januar 2016 23:00  
**Til:** [primsund@sum.dk](mailto:primsund@sum.dk); [pkh@sum.dk](mailto:pkh@sum.dk)  
**Cc:** Lotte Holmstrup <[lho@danskerhverv.dk](mailto:lho@danskerhverv.dk)>; Jeanette Rohd Gernsøe <[jrp@danskerhverv.dk](mailto:jrp@danskerhverv.dk)>  
**Emne:** VS: Høring vedrørende forslag til lov om elektroniske cigaretter m.v.

Til Sundheds- og Ældreministeriet,

Hermed følger Dansk Erhvervs høringssvar vedr. forslag til lov om elektroniske cigaretter m.v.

Med venlig hilsen

Lotte Engbæk Larsen  
Markedschef

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[LEL@DANSKERHVERV.DK](mailto:LEL@DANSKERHVERV.DK)



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**DANSK  
ERHVERV**

Dansk Erhverv er erhvervsorganisation og arbejdsgiverforening for fremtidens erhverv. Vi repræsenterer 17.000 virksomheder og 100 brancheorganisationer inden for handel, rådgivning, oplevelse, transport og service.



**Fra:** Patrick Kofod Holm [<mailto:pkh@sum.dk>]

**Sendt:** 22. december 2015 15:03

**Til:** '3f@3f.dk'; 'a@aarch.dk'; 'ac@ac.dk'; 'al@produktionsskoleledere.dk';  
'apotekerforeningen@apotekerforeningen.dk'; 'bestyrelserne@danskeerhvervsskoler.dk';  
'bfid@scanpharm.dk'; 'bof@homannlaw.dk'; 'brd@brd.dk'; 'b-sosu@sosu.dk'; 'da@da.dk'; 'dadl@dadl.dk';  
'df@friskoler.dk'; 'dfi@dkpharma.dk'; 'dh@handicap.dk'; 'di@di.dk'; 'dj@sctib.dk';  
'dk@designskolenkolding.dk'; 'dkuni@dkuni.dk'; 'd-r-c@d-r-c.dk'; 'dse@skoleelever.dk'; 'dsk@dsk.dk';  
'dsr@dsr.dk'; 'dssv@dssv.dk'; 'dtl@dtl.eu'; 'eeo@eeo.dk'; 'etf@etf.dk'; 'fa@fanet.dk'; 'fas@dadl.dk';  
'ff@farmakonom.dk'; 'fkf@kristne-friskoler.dk'; 'fms@fms.dk'; 'foa@foa.dk';  
'forbrugerombudsmanden@kfst.dk'; 'formand@dadafo.dk'; 'formand@danmarksvejlederforening.dk';  
'formand@gymbf.dk'; 'ftf@ftf.dk'; 'fysio@fysio.dk'; 'gymbf@gymbf.dk'; 'handel@hk.dk';  
'hej@friefagskoler.dk'; 'Helen.gerdrup.nielsen@regionh.dk'; 'hf@fadl.dk'; 'hjj@dbi-net.dk';  
'hoeringssager@danskerhverv.dk'; 'horesta@horesta.dk'; 'info@astma-allergi.dk'; 'info@cancer.dk';  
'INFO@CFU-NET.DK'; 'info@danskeerhvervsakademier.dk'; 'info@danskeerhvervsskoler.dk';  
'info@deoffentligetandlaeger.dk'; 'info@diabetes.dk'; 'info@efterskoleforeningen.dk';  
'info@efterskoleforeningen.dk'; 'info@fadd.dk'; 'info@igldk.dk'; 'INFO@KADK.DK'; 'info@kfumsoc.dk';  
'info@krifa.dk'; 'info@landboudngdom.dk'; 'info@lif.dk'; 'info@lunge.dk'; 'info@lunge.dk'; 'info@msk.dk';  
'info@nbl-landsforening.dk'; 'info@patientsikkerhed.dk'; 'info@pfl.dk'; 'info@pharmakon.dk';  
'info@privatehospitaler.dk'; 'info@privatskoleforening.dk'; 'info@rogfritmiljo.dk'; 'info@shipowners.dk';  
'info@smokesolution.com'; 'Info@sygeforsikring.dk'; 'info@tandlaegeforeningen.dk'; 'info\_dk@bat.com';  
'ing@fugleviglund.dk'; 'jo.ir@dsg.dk'; 'jpe@silkeborg.dk'; 'jts@danskerhverv.dk'; 'ka@ka.dk';  
'kd@kadk.dk'; 'kfs@sundkom.dk'; 'kfst@kfst.dk'; 'kk@kobenhavn.kirkenskorshaer.dk'; 'kl@kl.dk';  
'kontakt@cfh.ku.dk'; 'kontakt@dgsnet.dk'; 'kristen.kistrup@regionh.dk'; 'kundeservice@coop.dk';  
'Landselevbestyrelse@FOA.DK'; 'lederforeningen@sosu.dk'; 'lederne@danskeerhvervsskoler.dk';  
'lh@handelselever.dk'; 'lo@lo.dk'; 'los@los.dk'; 'lu@lus.dk'; 'mail@danskegymnasier.dk';  
'mail@danskegymnasier.dk'; 'mail@rektorforeningen.dk'; 'mail@simac.dk'; 'mail@soefartens.org';  
'martec@martec.nu'; 'medico@medicoindustrien.dk'; 'mf@mmf.dk';  
'moedrehjaelpen@moedrehjaelpen.dk'; 'nnf@nnf.dk'; 'oliver-twist@oliver-twist.dk';  
'pd@pharmadanmark.dk'; 'pd@pharmadanmark.dk'; 'plo@dadl.dk'; 'post@danske-landbrugsskoler.dk';  
'post@forhandlingsfaellesskabet.dk'; 'post@hjerterforeningen.dk'; 'post@lilleskolerne.dk'; 'post@skole-  
foraeldre.dk'; 'post@sundbynetvaerket.dk'; 'post@udsatte.dk'; 'private@gymnasier.dk';

'psa@humleby.dk'; 'psf@psf.nu'; 'pto@pto.dk'; 'ptu@ptu.dk'; 'regioner@regioner.dk'; 'REU@uvm.dk';  
'samfund@advokatsamfundet.dk'; 'sek@jordemoderforeningen.dk';  
'sekretariat@erhvervsskolelederne.dk'; 'shk@sundhedskartellet.dk'; 'sl@sl.dk'; 'ti@tobaksindustrien.dk';  
'tp@amu-vest.dk'; 'uc-dk@uc-dk.dk'; 'us@us-center.dk'; 'VEU-raadet@uvm.dk'; 'vuc@vuc.dk';  
'vuc@vuc.dk'; 'aams@aams.dk'; 'info@rigsrevisionen.dk'; 'dt@datatilsynet.dk'; [fertin@fertin.com](mailto:fertin@fertin.com)  
**Cc:** Mette Touborg Heydenreich <[mhe@sum.dk](mailto:mhe@sum.dk)>; Katrine Ring <[kari@sum.dk](mailto:kari@sum.dk)>; Dorthe Eberhardt  
Søndergaard <[des@sum.dk](mailto:des@sum.dk)>; Erich Erichsen <[eer@sum.dk](mailto:eer@sum.dk)>  
**Emne:** Høring vedrørende forslag til lov om elektroniske cigaretter m.v.

Hermed sendes vedhæftede forslag til lov om elektroniske cigaretter m.v. i høring. Der henvises til vedhæftede høringsbrev.

Med venlig hilsen

**Patrick Kofod Holm**

Fuldmægtig

Primær Sundhed, Ældrepolitik og Jura

Direkte tlf.: 72 26 95 09

Mail: [pkh@sum.dk](mailto:pkh@sum.dk)

Sundheds- og Ældreministeriet • Holbergsgade 6 •  
1057 København K • Tlf. 7226 9000 • Fax 7226 9001 • [www.sum.dk](http://www.sum.dk)





Sundheds- og Ældreministeriet  
Holbergsgade 6  
1057 København K

Pr. e-mail: [primsund@sum.dk](mailto:primsund@sum.dk) og [pkh@sum.dk](mailto:pkh@sum.dk)  
J.nr.: 1503812

22. januar 2016

## **Ændring af høringsvar vedr. høring over udkast til lovforslag om regulering af elektroniske cigaretter og genopfyldningsbeholdere**

Dansk Erhverv sender hermed ændring af høringssvar vedr. udkast til lovforslag om regulering af elektroniske cigaretter og genopfyldningsbeholdere og har følgende bemærkninger.

### **Kapitel 2 Anvendelse af elektroniske cigaretter med og uden nikotin**

Dansk Erhverv mener, at regulering af rygepolitikker vedr. elektroniske cigaretter skal være en del af lov om røgfrie miljøer og ikke stå i en lov om elektroniske cigaretter, idet det giver et ringe overblik over, hvad der kræves af arbejdsgiverne, når der er tale om ”rygning” på arbejdspladsen.

Dansk Erhverv mener derfor, at udkastets forslag om lovgivning af rygepolitikker vedr. elektroniske cigaretter skal udgå af forslaget og i stedet adresseres i loven om røgfri miljøer, hvor det naturligt og logisk hører hjemme, såfremt der er det fornødne sundhedsmæssige belæg for elektroniske cigaretters skadelige effekt på andre end rygeren.

Med det foreliggende vidensniveau om de sundhedsskadelige effekter af dampene, bør det følgelig ikke være et krav, at virksomheder, hvortil der er offentlig adgang som anført i udkastets § 4, skal indføre en rygepolitik vedr. elektroniske cigaretter. Denne beslutning bør overlades til virksomhederne selv. Et krav sådan ville i givet fald udgøre en ekstra administrativ byrde for de virksomheder, som skal revidere deres rygelov. Hertil kommer, at det er meget uklart, hvilke virksomheder, der er omfattet af ”offentlig adgang”.

Hvad angår døgninstitutioner og unges brug af elektroniske cigaretter, henføres til lov om røgfrie miljøer, jf. nedenfor.

Uddrag fra Lov om røgfri miljøer:

*Institutioner og skoler for børn og unge*

**§ 7.** På børneinstitutioner, skoler, opholdssteder og lign., der fortrinsvis har optaget børn og unge under 16 år, er det ikke tilladt for børn og unge samt elever at ryge på institutionens område.

*Stk. 2.* For døgninstitutioner, opholdssteder, kostskoler, efterskoler og lign., der fortrinsvis har optaget unge i 15-16 års alderen og derover, og som også fungerer som bolig for de unge, kan det besluttes, at det er tilladt, at de unge ryger i rygerum og på deres egne værelser.

**§ 8.** For personer, der ikke er omfattet af § 7, er det ikke tilladt at ryge på institutionens udendørsarealer, hvor børn og unge færdes.

*Stk. 2.* Det kan besluttet at indrette rygerum, hvor de pågældende kan ryge.

Det anføres i den forbindelse, at de ansattes mulighed for at ryge på området bør opretholdes, jf. § 8.

### **Afsluttende kommentarer**

Hvis der ikke tages højde for vores bemærkninger, forbeholder vi os retten til at komme med yderligere kommentarer, samt opfordrer til, at det sikres, at de høringsparter, som normalt bidrager ved drøftelser og ændringer af loven om røgfri miljøer, er inddraget og opmærksomme på at regulering af rygepolitikker på arbejdspladser også indgår i udkastet til lovforslag.

Dansk Erhverv uddyber gerne overstående, hvis det har interesse.

Med venlig hilsen

**Lotte Engbæk Larsen**

**From:** Kristen Kistrup  
**Sent:** 11 Apr 2016 10:07:33 +0000  
**To:** Majken Toft Larsen  
**Subject:** VS: Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Kære Majken Toft Larsen.  
Dansk Selskab for Distriktpsychiatri har ikke kommentarer til udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Med venlig hilsen

Kristen Kistrup  
Centerchef, formand for Dansk Selskab for Distriktpsychiatri

Direkte: 38643701  
Mail: [kristen.kistrup@regionh.dk](mailto:kristen.kistrup@regionh.dk)

Psykiatrisk Center Frederiksberg  
Region Hovedstadens Psykiatri  
Ndr. Fasanvej 57-59  
2000 Frederiksberg

Tlf: 38643700  
Web: [psykiatri-regionh.dk/centre/Psykiatrisk Center Frederiksberg](http://psykiatri-regionh.dk/centre/Psykiatrisk%20Center%20Frederiksberg)

---

**Fra:** Majken Toft Larsen [mailto:MTL@sik.dk]  
**Sendt:** 7. april 2016 13:51  
**Til:** Majken Toft Larsen  
**Emne:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Hermed sendes udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. i høring.

Venlig hilsen



**Majken Toft Larsen**  
Jurist, fuldmægtig

E-mail: [MTL@sik.dk](mailto:MTL@sik.dk)

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Erhvervs- og Vækstministeriet

Sikkerhedsstyrelsen

Journalnr. 615-10-00001 og

Journalnr. 615-20-00001

Glostrup, 4. maj 2016

Bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v. og bekendtgørelse om indberetning af tobaksvarer og urtebaserede rygeprodukter samt anmeldelse af nye kategorier af tobaksvarer m.v.

Dansk Selskab for Folkesundhed (DSFF) takker for muligheden for at kommentere de fremsendte forslag. DSFF vurderer, at indholdet er meget teknisk og har ikke yderligere kommentarer til dette.

Med venlig hilsen

Torben Jørgensen

Formand

Dansk Selskab for Folkesundhed

**From:** Thomas Kurz Ankersen  
**Sent:** 12 Apr 2016 08:01:14 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Cc:** Jesper Jans; Ingrid Behrndt Andersen  
**Subject:** Høringssvar vedrørende sags.nr.: 615-10-00001 - Høring overudkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Kære Branka Klisura

Vedhæftet er Danske Erhvervsskoler – Bestyrelserne og Danske Erhvervsskoler – Ledernes fælles høringssvar over fremsendte udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Jeg ønsker en fortsat god dag.

Med venlig hilsen

Thomas K. Ankersen | Chefkonsulent



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[www.danskeerhvervsskoler.dk](http://www.danskeerhvervsskoler.dk)

**From:** Ulrika Calmar Folkmann-Schjerbeck  
**Sent:** 2 May 2016 15:54:22 +0200  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Subject:** J.nr. 615-10-00001 (Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.) (FO 16/04684)

Forbrugerombudsmanden har ingen bemærkninger til udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Med venlig hilsen  
På Forbrugerombudsmandens vegne

**Ulrika Calmar Folkmann-Schjerbeck**

Procedør, specialkonsulent  
Direkte tlf.: 4171 5317  
E-mail: [ucf@kfst.dk](mailto:ucf@kfst.dk)



Carl Jacobsens Vej 35  
2500 Valby  
Tlf. +45 4171 5151

---

**Fra:** Majken Toft Larsen  
**Sendt:** 7. april 2016 13:51  
**Til:** Majken Toft Larsen  
**Emne:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Hermed sendes udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. i høring.

Venlig hilsen



**Majken Toft Larsen**  
Jurist, fuldmægtig

E-mail: [MTL@sik.dk](mailto:MTL@sik.dk)

Sikkerhedsstyrelsen  
Nørregade 63  
6700 Esbjerg  
Tlf.: 33 73 20 00  
[www.sik.dk](http://www.sik.dk)

*Denne e-mail og enhver vedhæftet fil er fortrolig og alene tiltænkt modtageren. Såfremt De ikke er rette modtager, vil adgang til e-mailen være ubeføjet, og enhver udnyttelse eller videregivelse af e-mailens indhold være uretmæssig og potentielt i strid med lovgivningen. Såfremt De ikke er rette modtager, bedes De venligst omgående underrette os og derefter slette e-mailen og enhver vedhæftet fil. På forhånd tak.*



**From:** LANDSELEVBESTYRELSEN  
**Sent:** 3 May 2016 12:46:04 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Subject:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. jorunalnr. 615-10-00001

Kære Sikkerhedsstyrelse

Sikkerhedsstyrelsen har ved e-mail af 12. april 2016, anmodet Landselevbestyrelserne for social- og sundhedsuddannelsen og for pædagogiskassistent uddannelsen om eventuelle bemærkninger til høring over udkast til " til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv."

Pædagogiskassistent elevbestyrelsen og social- og sundhedselevbestyrelsen har ikke bemærkninger til udkastet.

Venlig hilsen

Heidi Leen

Konsulent for pædagogiskassistent elevbestyrelsen og social- og sundhedselevbestyrelsen

Staunings Plads 1-3 | DK-1790 København V

Telefon direkte: 4697 2429 | Mobil: 2637 4149



De private sociale tilbud

Emdrupvej 115 A 5. etage  
2400 København NV

Tlf. nr. +45 7023 3400  
E-mail: los@los.dk  
CVR nr. 15906987

[www.los.dk](http://www.los.dk)

Sikkerhedsstyrelsen  
Nørregade 63  
6700 Esbjerg

Århus den 28. april 2016

**Vedr. Høring over udkast til Bekendtgørelse om anmeldelse af elektroniske  
cigaretter og genopfyldningsbeholdere mv.**

LOS – De private sociale tilbud takker for muligheden for at afgive høringssvar til udkast til  
Bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

LOS har ingen kommentarer til udkastet.

Med venlig hilsen

Karina Hjerimitslev

Jurist, LOS



**From:** rr@rigsrevisionen.dk  
**Sent:** 2 May 2016 12:22:33 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Cc:** Service-05kt  
**Subject:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. (j.nr. 6507)

Til Sikkerhedsstyrelsen

Rigsrevisionen modtog d. 7. april 2016 høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. (journalnr. 615-10-00001).

Rigsrevisionen har gennemgået lovforslaget for bestemmelser om regnskab og revision i henhold til Rigsrevisorlovens §§ 7 og 10. Rigsrevisionen har ikke bemærkninger til udkastet.

Eventuelle spørgsmål kan stilles til undertegnede på telefon 33 92 84 46 eller via e-mail til [rr@rigsrevisionen.dk](mailto:rr@rigsrevisionen.dk) med anførelse af det i overskriften anførte journalnummer.

Bekræft venligst, at denne e-mail er modtaget.

Med venlig hilsen

Peter Kjær Strandlyst  
Specialkonsulent, COR-revisor

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RIGSREVISIONEN



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---

**From:** Kirsten Fly Malling  
**Sent:** 4 May 2016 12:12:36 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Cc:** Bjarne Graabech Sørensen; Karen Heebøll; Jørgen Schou; Annette Schmidt; Lone Wichmann  
**Subject:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.

Sikkerhedsstyrelsen

Styrelsens j.nr. 615-10-00001  
SDU's sagsnr. 16/107

SDU har ingen bemærkninger til ovenstående høring.

Venlig hilsen

**Kirsten Fly Malling**  
Kontorfuldmægtig  
Rektorsekretariatet

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**From:** Janni Wester-Andersen  
**Sent:** 3 May 2016 11:03:44 +0000  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Subject:** VS: Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Til Sikkerhedsstyrelsen

Søfartens Ledere har ingen indvendinger eller bemærkninger til Høringen over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Med venlig hilsen

For direktør Fritz Ganzhorn

**Janni Wester-Andersen**

Assistent

[jwa@soefartens.org](mailto:jwa@soefartens.org)

(+45) 33455565

(+45) 33 45 55 71 (direkte)

(+45) 23 46 59 52 (mobil)



**Søfartens Ledere**

Havnegade 55

1058 København K



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**Fra:** Søfartens Ledere [<mailto:SofartensLedere@soefartens.org>]

**Sendt:** 7. april 2016 13:51

**Til:** Lise Lammers; Janni Wester-Andersen

**Emne:** VS: Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

-----  
**Fra:** Majken Toft Larsen [[SMTP:MTL@SIK.DK](mailto:SMTP:MTL@SIK.DK)]

**Sendt:** 7. april 2016 13:51:10

**Til:** Majken Toft Larsen

**Emne:** Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

**Videresendt automatisk vha. en regel**

Hermed sendes udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv. i høring.

Venlig hilsen



**Majken Toft Larsen**

Jurist, fuldmægtig

E-mail: [MTL@sik.dk](mailto:MTL@sik.dk)

Sikkerhedsstyrelsen

Nørregade 63

6700 Esbjerg

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[www.sik.dk](http://www.sik.dk)

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# E-cigaretter

## Høringssvar med bemærkninger

Bagger-Sørensen Gruppen

BECIG – Brancheforeningen for E-cigaret forhandlere

DADAFO – Dansk e-Damper Forening

Erhvervsstyrelsen, Team Effektiv Regulering

Esug.dk

Forbrugerrådet Tænk

Henrik Herskind

Kræftens Bekæmpelse

Philip Morris ApS

Tobaksproducenterne

Maj 2016



# Høring vedr. *Bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.*

Bagger-Sørensen Gruppen<sup>1</sup> har modtaget høringen vedr. *Bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.*

## 1. Bemærkninger til enkelte bestemmelser

**§ 6:** Der lægges i stk. 2 op til, at ingredienser anvendt i mængder på over 0,1% af den færdigformulerede væske ikke anses for at være en forretningshemmelighed eller en fortrolig oplysning.

Vi mener, at dette er dybt problematisk, da producenterne vil blive tvunget til at offentliggøre e-væskernes fulde ingrediensliste, hvilket gør kopiering af opskrifter let. På længere sigt kan det holde producenter ude af markedet og svække incitamentet til innovation.

Vi opfordrer derfor til, at ingredienser på under 1% af den færdigformulerede væske anses som værende en forretningshemmelighed og omgivet af fuld fortrolighed. Der findes ikke andre kategorier inden for den danske lovgivning (tobak, lægemidler, fødevarer), hvor eksempelvis smagsstoffers sammensætning ikke anses for at være forretningshemmeligheder. Smagsstofferne sammensætning er som oftest tredjeparts forretningshemmelighed og kan i fortrolighed blive oplyst til myndighederne.

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<sup>1</sup> Bagger-Sørensen Gruppen har mange års erfaring med produktion af nikotinholdige produkter af høj kvalitet. Bagger-Sørensen Gruppen ejer virksomheden Fertin Pharma A/S, der er en af de ledende selskaber på verdensmarkedet for nikotintyggegummi. I Okono A/S, der er affilieret til Bagger-Sørensen Group, markedsfører man i dag e-cigaretten nordik® i den danske detailhandel. E-væsken i nordik® bliver produceret under farmaceutiske forhold på en fabrik i Vejle.

# Høringssvar fra



**'Bekendtgørelse om anmeldelse af elektroniske  
cigaretter og genopfyldningsbeholdere mv.'**

**Klarup, d. 4. maj 2016**

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## Indledende kommentarer

Vi vil i det dette høringssvar gennemgå 'Bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.'. Vi vil give vores bud på hvilke elementer der bør korrigeres, for at få en proportionel regulering af det danske marked for elektroniske cigaretter – med specifik fokus på de foreslåede gebyrtakster for anmeldelse af produkter.

Overordnet set, så er disse bekendtgørelser en oversættelse af de notater EU-Kommissionen har udsendt, og derfor er der ikke meget i dem, der vil kunne rettes. Det er dog vores opfattelse, at der fra Sikkerhedsstyrelsens side mangler en klar viden om de produkter, man med disse bekendtgørelser ønsker at kontrollere. Det afspejler sig også i den manglende detaljegrad i bekendtgørelserne, som i vid udstrækning er åbne for fortolkning. Det finder vi selvfølgelig dybt beklageligt; og vi finder det også beklageligt, at Sikkerhedsstyrelsen og Sundhedsstyrelsen ikke i videre udstrækning har brugt den branche- og produktviden som BECIG har stillet til rådighed.

Denne mangel på kompetence og inddragelse af branchen har ført til, at der er ét sted hvor Danmark kommer til at skille sig markant ud fra resten af EU – og det er på størrelsen af gebyret for anmeldelse af produkter. Det er med stor beklagelse, at der fra Sikkerhedsstyrelsens side ikke har været lydhørhed over for dette problem. Dette står også i kontrast til de udmeldinger der kom fra Sikkerhedsstyrelsen i forbindelse med vores møde d. 4. februar. Et gebyr på 36.900 kr. pr. produkt er ude af proportioner, i et marked med i omegnen af 10.000 produkter – selv ud fra de mest konservative skøn.

I andre europæiske lande har man inddraget branchen for at finde en passende gebyrstørrelse, dette har man desværre ikke gjort i Danmark. Der har man i stedet baseret gebyret på en rapport fra WHO, som man på det groveste har fejllæst eller mistolket – enten bevidst eller ubevidst.

Vores høringssvar vil derfor indeholde en gennemgang af WHO rapporten fra 2014 og en gennemgang af fremgangsmåden i andre lande i EU. Ligeledes vil der være en gennemgang af en model for gebyrpriser, som både er proportionel og på linje med gebyrpriser for andre lande i EU. Denne model vil inddrage eksempler fra nogle af BECIG's medlemmer. Vi forventer, selvfølgelig, at vores høringssvar vil give anledning til ændring af gebyrprisen for anmeldelse af produkter.

På vegne af Brancheforeningen for E-cigarett Forhandlere

**Michael Larsen, formand**



## Gebyrpriser baseret på fejlfortolket WHO rapport

Til BECIG's møde med Sikkerhedsstyrelsen d. 4. februar 2016, blev vi informeret om, at årsagen til, at man har foreslået et gebyr for anmeldelse af produkter på 36.900 kr. er, at en WHO rapport fra 2014 har estimeret, at der er 466 produkter på verdensmarkedet i dag. Dette fandt vi fra BECIG's side utroligt interessant. Hvordan kan WHO estimere, at der er 466 produkter på markedet, når alene brancheforeningens medlemmer har et varesortiment på mere end 10.000 produkter?

Det viser sig dog også, at man blot ved at læse WHO's rapport, bliver en hel del klogere på hvad WHO rent faktisk har skrevet. De skriver, ret tydeligt, at de estimerer, at der i 2014 er 466 e-cigaret brands på markedet (Bilag 1). For personer der ikke er bevidste om forskellen

*"Lego er ét brand – men de fleste er bevidste om, at det ikke betyder, at de kun har ét produkt."*

mellem et brand og et produkt, så kan det eksemplificeres med virksomheden Lego. Lego er ét brand (for de kyndige har de dog mange subbrands) – men de fleste er bevidste om, at det ikke betyder, at de kun har ét produkt.

WHO's rapport angiver også tydeligt en kilde til deres estimat på de 466 brands. Det er en videnskabelig artikel af Shu-Hong Zhu et. al. med titlen "Four hundred and sixty brands of e-cigarettes and counting". I den står der, ja allerede i abstractet, at de 466 brands har mere end 7764 forskellige e-væsker i sortimentet (Bilag 2). Altså, 7764 forskellige e-væsker, man er her ikke engang begyndt at tælle hardware, altså selve e-cigaretten – og sidst men ikke mindst – så er det to år siden. Verden har ikke stået stille siden.

Hvorfor er dette tal så vigtigt? Jo, da Sikkerhedsstyrelsen og Sundhedsstyrelsen ønsker hvert produkt – hardware og e-væske – anmeldt i Danmark, så har det stor betydning hvor mange produkter der er på markedet. Forskellen er slående. Med en gebyrpris på 36.900 kr. for anmeldelse af et produkt, og med 466 produkter på markedet, vil udgiften for branchen (og gebyrindtægterne for Sikkerhedsstyrelsen) være ca. 17 mio. kr. Tager man til gengæld det faktiske antal produkter på markedet i Danmark, så vil beløbet lande på 465 mio. Dette beløb er fuldstændig ude af proportioner.

Fra BECIG's side finder vi det bekymrende, at danske myndigheder ikke er i stand til at læse en forholdsvis enkelt opstillet og kort rapport fra WHO. Yderligere, så må det forventes, at embedsmænd i hhv. Sikkerhedsstyrelsen, Sundhedsstyrelsen og Sundheds- og Ældreministeriet er i stand til at læse kildehenvisninger. Når myndighederne har fået en opgave som denne, så forventes det fra branchens side, at disse myndigheder gør deres yderste for at forstå deres opgave. Det forventes, at man fra myndighedernes side læser og forstår relevante rapporter, og ikke alene baserer deres antagelser og rådgivning til politikerne på von hørensagen.

## Proceduren i England og i EU

I modsætning til Danmark, har man i England valgt en tilgang til gebyrpriserne på anmeldelser, der baserer sig på realistiske estimater fra branchen og andre interessenter. Man har gennem en demokratisk og fair procedure, en høring, spurgt industrien om hvor mange produkter de ved en given pris ønsker at anmelde (Bilag 3).

Udgangspunktet for denne engelske høring var en gebyrpris på 220 £ (2.100 kr.) for indledende anmeldelse, 80 £ (760 kr.) for en ændring af anmeldelsen, samt et årligt tilbagevendende gebyr for opretholdelse af anmeldelsen på 60 £ (570 kr.).

Men med de tilbagemeldinger der kom, samt den enorme interesse der var for at anmelde produkter, ikke overraskende, så er gebyrerne blevet justeret ned. De britiske sundhedsmyndigheder (MHRA) forventer nu, at der alene det første år, vil bliver anmeldt ca. 14.000 produkter (Bilag 3). Det er et estimat, der ligger tæt op af, hvad BECIG mener branchen i Danmark ønsker at anmelde – givet man i Danmark justerer gebyrpriserne, så de tilsvare de engelske. Det betyder derfor, at gebyrpriserne for anmeldelse af produkter i England er endt på 150 £ (1.430 kr.) for indledende anmeldelse, 80 £ (760 kr.) for en ændring af anmeldelsen, samt et årligt tilbagevendende gebyr for opretholdelse af anmeldelsen på 60 £ (570 kr.) (Bilag 4).

At man i England er endt på en gebyrpris så langt fra den der er foreslået i Danmark, vidner om hvor langt man er fra virkeligheden hos de danske myndigheder. Vi kan her risikere, i

*De foreslåede gebyrpriser i Danmark er 2.600 % højere end i England – for samme ydelse.*

forsøget på at implementere et EU-direktiv der skal: "...indbyrdes tilnærme lovgivningen medlemsstaterne imellem...", at lave en lovgivning og pålægge branchen nogle gebyrstørrelser, der vil have den diametralt modsatte effekt. EU's Tobaksvaredirektiv

artikel 20, stk. 2 G siger: "Medlemsstaterne kan opkræve forholdsmæssige gebyrer af fabrikanter og importører for modtagelse, lagring, håndtering og analyse af oplysninger, som de modtager." (Bilag 5)

Med forholdsmæssige gebyrer menes der ikke gebyrstørrelser, der er næsten 26 gange så store i forhold til andre EU lande. Dette ville på intet tidspunkt blive accepteret i EU, i det tilfælde at Danmark stædigt fastholder gebyrstørrelser, der vil ødelægge det danske marked for e-cigaretter, og sætte barrierer op for fri konkurrence medlemsstaterne imellem. At lave den type handelsbarrierer for en branche – hvis produkter til fulde lever op til gældende lov – vil øjeblikkeligt føre til en sag ved EU-domstolen; og det bør fra de danske myndigheders side, ikke være nogen ønskelig øvelse.

## BECIG's gebyrforslag

Vi vil i det følgende opstille eksempler på prisberegninger, både hvis gebyrpriserne ikke ændres (36.900 kr.), samt hvis gebyrpriser ændres til 1.500 kr. for anmeldelse af et produkt, samt et årligt gebyr for opretholdelse af anmeldelse på 600 kr. Det er BECIG's vurdering, at et gebyr på 1.500 kr. er proportionelt, samt at det vil betyde, at Sikkerhedsstyrelsen med en stor sikkerhedsmargin vil nå et beløb på minimum 10,2 mio. for den samlede danske branche.

Udregningerne er alene lavet ud fra information fra BECIG's medlemmer. De er lavet ud fra hvad BECIG's medlemmers nuværende produktsortiment er, samt ud fra, hvad BECIG's medlemmer ønsker at anmelde, såfremt gebyret bliver sat til 1.500 kr. pr. anmeldelse. Det skal bemærkes, at vi ca. estimerer, at BECIG's medlemmer udgør 35% af det samlede danske marked.

### Prisberegning

Produkter	Antal	Nikotinstyrker	Total antal	Pris	Total Pris
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#### Nuværende produktsortiment hos BECIG's medlemmer

Væsker	2.380	5	11.900	36.900 kr.	439.110.000 kr.
Hardware	700		700	36.900 kr.	25.830.000 kr.

<b>Pris for anmeldelse</b>					<b>464.940.000 kr.</b>
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#### Prisestimering for BECIG's medlemmer - højt gebyr (ud fra forventede anmeldelser ved proportionelt gebyr)

Væsker	1.600	4	6.400	36.900 kr.	236.160.000 kr.
Hardware	320		320	36.900 kr.	11.808.000 kr.

<b>Pris for anmeldelse</b>					<b>247.968.000 kr.</b>
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#### Forventede anmeldelser fra BECIG's medlemmer - proportionelt gebyr

Væsker	1.600	4	6.400	1.500 kr.	9.600.000 kr.
Hardware	320		320	1.500 kr.	480.000 kr.

<b>Pris for anmeldelse</b>					<b>10.080.000 kr.</b>
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Som det ses i tabellen ovenfor, så vil BECIG's medlemmer alene, såfremt gebyret for anmeldelse af produkter sættes til 1.500 kr., anmelde produkter for over 10 mio. kr. det første år. Det betyder, at BECIG's medlemmer næsten vil anmelde produkter for det beløb Sikkerhedsstyrelsen forventer at få ind i gebyrer.

Antallet af produkter BECIG's medlemmer forventer at anmelde, ligger på lige knapt halvdelen af det antal produkter man forventer anmeldt i England.

I det følgende har vi valgt seks medlemmer af BECIG, til at lave en detaljeret udregning på det antal produkter de ønsker at notificere, såfremt gebyret for anmeldelse af produkter sættes til 1.500 kr.. Det skal bemærkes, at disse seks medlemmer udgør knap 20% af BECIG's medlemmer.

De er valgt, da de repræsenterer de forskellige medlemmer der er i BECIG, herunder væskeproducenter, importører, samt forhandlere der importerer eget hardware brand og har deres egne væskeserier med variende nikotinstyrker.

### Beregning for seks af BECIG's medlemmer

<i>Produkter</i>	<i>Antal</i>	<i>Nikotinstyrker</i>	<i>Total antal</i>	<i>Pris</i>	<i>Total Pris</i>
<b>Forhandler nr. 1</b>					
Væsker	76	4	304	1.500 kr.	456.000 kr.
Væsker	30	6	180	1.500 kr.	270.000 kr.
Hardware inkl. eget brand	14		14	1.500 kr.	21.000 kr.
<b>Total forhandler nr. 1</b>					<b>747.000 kr.</b>
<b>Forhandler nr. 2</b>					
Væsker	50	4	200	1.500 kr.	300.000 kr.
Væskebaser	10	2	20	1.500 kr.	30.000 kr.
Hardware inkl. eget brand	6		6	1.500 kr.	9.000 kr.
<b>Total forhandler nr. 2</b>					<b>339.000 kr.</b>
<b>Forhandler nr. 3</b>					
Væsker	35	6	210	1.500 kr.	315.000 kr.
Væskebaser	6	3	18	1.500 kr.	27.000 kr.
Hardware inkl. eget brand	8		8	1.500 kr.	12.000 kr.
<b>Total forhandler nr. 3</b>					<b>354.000 kr.</b>
<b>Forhandler nr. 4</b>					
Væsker	120	4	480	1.500 kr.	720.000 kr.
Væskebaser	6	6	36	1.500 kr.	54.000 kr.
Hardware inkl. eget brand	22		22	1.500 kr.	33.000 kr.
<b>Total forhandler nr. 4</b>					<b>807.000 kr.</b>



**Forhandler nr. 5**

Væsker	30	4	120	1.500 kr.	180.000 kr.
Væskebaser	4	4	16	1.500 kr.	24.000 kr.

**Total forhandler nr. 5** **204.000 kr.**

**Forhandler nr. 6**

Væsker	75	6	450	1.500 kr.	675.000 kr.
Væskebaser	5	6	30	1.500 kr.	45.000 kr.
Hardware	260		260	1.500 kr.	390.000 kr.

**Total forhandler nr. 6** **1.110.000 kr.**

**Total for 20% af BECIG's medlemmer** **3.561.000 kr.**

Som det ses ovenfor har vi udvalgt seks meget forskellige typer forhandlere. Der er nogle, der baserer sig på import af hardware, nogle på væskeproduktion, mens andre er spredt mere ud over de forskellige kategorier. Men fælles for dem alle, så ønsker de at anmelde et stort udvalg af produkter, såfremt de danske priser harmoniseres med resten af EU.

Til mødet mellem BECIG og Sikkerhedsstyrelsen d. 4. februar 2016, blev det af Sikkerhedsstyrelsen nævnt, at man ønsker at teste ca. 50% af alle e-væsker der bliver anmeldt i Danmark. Det finder vi fra BECIG's side absolut unødvendigt og ikke proportionelt. Vi ved, at de store væskeproducenter der ønsker at anmelde e-væsker i EU, får lavet alle de nødvendige tests i forbindelse med deres overensstemmelsescertifikater i forhold til Tobaksvaredirektivet. Det betyder, at disse tests vil blive fremsendt sammen med anmeldelsen af e-væskerne.

Vi estimerer at en pris på 1.500 kr. for anmeldelse af et produkt, samt et årligt opretholdelsesgebyr på 600 kr. er proportionelt, og vil føre til en fortsat udvikling af det danske marked for e-cigaretter. Vi mener også, at vi med disse udregninger har præciseret, at et gebyr på 1.500 kr. for anmeldelse af produkter vil betyde, at Sikkerhedsstyrelsen med en sikker margin vil opnå de 10,2 mio. kr., som Sikkerhedsstyrelsen anslår det koster at drive anmeldelsessystemet og de tilhørende kontroltiltag.

## Konsekvenser hvis gebyrprisen ikke sænkes

Såfremt gebyret ikke sænkes til de foreslåede 1.500 kr. for anmeldelse af et produkt, og 600 kr. i årlig opretholdelse for anmeldelsen, så vil BECIG's medlemmer anmelde meget få produkter. De 36.900 kr. pr. produkt – når der er mere 12.600 produkter i sortimentet hos BECIG's medlemmer – vil simpelthen være en alt for stor byrde. At pålægge en branche en gebyrbyrde på ca. 465 mio. kr. fører blot til, at branchen finder andre måder at sælge produkterne.

Sikkerhedsstyrelsen vil derfor opleve, at alene nikotinbaser uden smag, i en enkelt nikotinstyrke tæt på de maksimale 20 mg. vil blive anmeldt af BECIG's medlemmer, og derefter vil man frit sælge aromastofferne som forbrugerne selv kan tilsætte deres nikotinbaser. Markedet vil derfor udvikle sig til et såkaldt selvblander marked. Det er et scenarie vi ikke ønsker fra BECIG's side, da det vil betyde et fuldstændig ukontrolleret marked. Men med de foreslåede gebyrpriser på 36.900 kr. er det desværre den vej markedet vil gå.

Derudover vil de foreslåede høje gebyrpriser kunne betyde lukningen af mange danske specialiserede e-cigaret forhandlere. Det vil kunne koste mange hundrede tabte arbejdspladser. Inden for e-cigaret erhvervet er der utroligt mange førstegangs selvstændige, som har brugt denne branche til at skabe en sund forretning – en forretning der nu er truet af gebyrer, der uden sammenligning er de største i EU.

Ikke alene for den etablerede branche vil de foreslåede høje gebyrer få konsekvenser. På det illegale marked for nikotin vil man se en enorm opblomstring. Myndighederne tror forkert,

*"Det danske marked vil blive  
oversvømmet med billig, næsten  
100% ren og livsfarlig nikotin."*

hvis de tror, at det foreslåede kontrolregime, vil lukke ned for import af så meget som 99,9% ren nikotin fra f.eks. Kina. Enhver forbruger, eller andre med lysten til det, kan, for meget billige penge, importere

dette i endda store mængder – leveret direkte til døren. Frem for at skabe kontrollerede forhold på markedet, kan disse foreslåede høje gebyrer betyde, at det danske marked vil blive oversvømmet med billig, næsten 100% ren og livsfarlig nikotin. Det endda i hænderne på folk uden den fornødne viden om hvordan dette skal håndteres.

## En kort opsummering

- BECIG ønsker gebyret for anmeldelse af et produkt sat til 1.500 kr. og 600 kr. i årligt opretholdelsesgebyr. De af Sikkerhedsstyrelsen foreslåede gebyrtakster er ude af proportioner, er ikke forlignelige med intentionen i Tobaksvaredirektivet og er langt fra de gebyrtakster man f.eks. ser i England.
- Hvis gebyret sættes til 1.500 kr. vil alene BECIG's medlemmer anmelde ca. 6.720 produkter det første år. Det vil betyde gebyrindtægter til Sikkerhedsstyrelsen på ca. 10 mio. BECIG's medlemmer står for ca. 35% af det danske marked, og dermed kan Sikkerhedsstyrelsen forvente langt flere anmeldelser.
- Sikkerhedsstyrelsen har fejllæst eller mistolket den WHO rapport, der ligger til grund for gebyrsatsen på de 36.900 kr. for anmeldelse af et produkt. Det er ikke acceptabelt, at en myndighed ikke nærlæser de dokumenter, der ligger til grund for en så markant indgriben i et etableret marked.
- I England var udgangspunktet et gebyr 2.100 kr. for anmeldelse af et produkt. Det har man allerede sænket til 1.430 kr. som følge af de tilkendegivelser, der er kommet fra branchen, om mængden af produkter der ønskes anmeldt. I England forventer man, at der det første år bliver anmeldt 14.000 produkter. Det står i skærende kontrast til Danmark, hvor man ikke har hørt branchen, og stik modsat branchen kun forventer at 466 produkter vil blive anmeldt.
- Hvis gebyret fastholdes på de 36.900 kr. vil branchen anmelde meget få produkter. Man vil alene anmelde nikotinbaser og sælge aromaerne separat. Det vil betyde, at forbrugerne modsat intentionen vil få produkter, der ikke er testede, og som ikke overholder de standarder branchen ønsker. Markedet for aromaer og e-væsker vil dermed blive fuldstændig ukontrolleret, og det alene grundet tiltag fra myndigheder, der i udgangspunktet havde en anden intention.
- Hvis gebyret fastholdes på de 36.900 kr. er der stor risiko for, at det illegale marked får en enorm opblomstring. Det er nemt og næsten uden risiko at importere så meget som 99,9% ren nikotin hjem fra bl.a. Kina. Denne livsfarlige koncentration af nikotin vil derefter blive anvendt af personer uden den fornødne evne til at håndtere det korrekt.

## Bilag

### Bilag 1 – WHO/FCTC Rapport 2014



Conference of the Parties to the  
WHO Framework Convention  
on Tobacco Control

Sixth session  
Moscow, Russian Federation, 13–18 October 2014  
Provisional agenda item 4.4.2

FCTC/COP/6/10  
21 July 2014

## Electronic nicotine delivery systems

### Report by WHO

#### INTRODUCTION

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fifth session (Seoul, Republic of Korea, 12–17 November 2012) to the Convention Secretariat to invite WHO to examine emerging evidence on the health impacts of electronic nicotine delivery systems (ENDS) use and to identify options for their prevention and control, for consideration at the sixth session of the COP.<sup>1</sup> This report incorporates the December 2013 deliberations and scientific recommendations on ENDS by the WHO Study Group on Tobacco Product Regulation (TobReg), and analysis from a recent WHO survey on tobacco products.<sup>2</sup>

2. ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased. Whereas some experts welcome ENDS as a pathway to the reduction of tobacco smoking, others characterize them as products that could undermine efforts to denormalize tobacco use. ENDS, therefore, represent an evolving frontier, filled

<sup>1</sup> See decision FCTC/COP5(10).

<sup>2</sup> The WHO tobacco products survey on smokeless, electronic nicotine delivery systems, reduced ignition propensity cigarettes, and novel tobacco products was sent to all WHO Member States. A total of 90 WHO Member States, including 86 Parties to the WHO FCTC, had responded to the survey as at 9 April 2014. These countries are: Australia, Austria, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Bhutan, Bolivia (Plurinational State of), Botswana, Brazil, Brunei Darussalam, Cambodia, Canada, Chile, China, Colombia, Congo, Costa Rica, Croatia, Czech Republic, Djibouti, Dominica, Ecuador, Egypt, Estonia, Fiji, Finland, France, Gabon, Georgia, Ghana, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Japan, Jordan, Kenya, Kuwait, Lao People's Democratic Republic, Latvia, Lebanon, Lithuania, Malaysia, Maldives, Mali, Mauritania, Mongolia, Morocco, Myanmar, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Philippines, Poland, Qatar, Republic of Korea, Russian Federation, Slovakia, South Sudan, Spain, Sudan, Suriname, Sweden, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, Tuvalu, United Arab Emirates, United States of America, Uruguay, Uzbekistan, Viet Nam, and Zambia.



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with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates. The evidence and recommendations presented in this report are therefore subject to rapid change.

#### PRODUCT DESIGN AND CONTENTS

3. ENDS, of which electronic cigarettes are the most common prototype, deliver an aerosol by heating a solution that users inhale. The main constituents of the solution by volume, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents.
4. Although some ENDS are shaped to look like their conventional tobacco counterparts (e.g. cigarettes, cigars, cigarillos, pipes, or hookahs), they also take the form of everyday items such as pens, USB memory sticks, and larger cylindrical or rectangular devices.
5. Battery voltage and unit circuitry differences can result in considerable variability in the products' ability to heat the solution to an aerosol and, consequently, may affect delivery of nicotine and other constituents, and may contribute to the formation of toxicants in the emissions.
6. User behaviour may affect nicotine absorption – length of puffs, depth of inhalation and frequency of use may be factors. However, while a faster, deeper puff increases nicotine delivery from a conventional cigarette, it might diminish it from ENDS due to cooling of the heating element.
7. In addition to manufacturer differences, some users modify products at home to alter delivery of nicotine and/or other drugs. Products vary widely in the ease with which they can be modified and the ease with which they can be filled with substances other than nicotine solutions.

#### THE ENDS MARKET

8. The use of ENDS is apparently booming. It is estimated that in 2014 there were 466 brands<sup>1</sup> and that in 2013 US\$ 3 billion was spent on ENDS globally. Sales are forecasted to increase by a factor of 17 by 2030.<sup>2</sup> Despite this projection, transnational tobacco companies are divided about the prospects of the growth of ENDS sales and some companies have reported a slowdown in sales in some markets.<sup>3,4,5</sup> There are no data on ENDS use at the global level and for many countries. However, data mainly from North America, the European Union (EU) and Republic of Korea indicate that ENDS use at least doubled among both adults and adolescents from 2008 to 2012.<sup>6</sup> In 2012, 7% of EU citizens aged 15 years and over had tried electronic cigarettes. However, only 1% of the total population used them regularly.<sup>7</sup> In 2013, 47% of smokers and ex-smokers in the United States of

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<sup>1</sup> Zhu S-H, Sun JY, Bonnevie E, Cummins SE, Gamst A, Yin L, Lee M. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control*. 2014;23:iii3–iii9. doi:10.1136/tobaccocontrol-2014-051670.

<sup>2</sup> The tobacco industry at a crossroads: cigarettes growth falters as focus falls on alternatives. *Euromonitor international*. July 2013

<sup>3</sup> Evans P. E-cigarettes are the future? Not so fast, says BAT's boss. *Wall Street Journal*. 30 July 2014 (<http://blogs.wsj.com/corporate-intelligence/2014/07/30/e-cigs-are-the-future-not-so-fast-says-bats-boss/>)

<sup>4</sup> Prior A. Lorillard profit down as e-cigarette sales drop: electronic cigarette sales tumble 35%, offsetting slight increase in traditional cigarettes. *Wall Street Journal*. 30 July 2014 (<http://online.wsj.com/articles/lorillard-profit-down-as-e-cigarette-sales-drop-1406720447>).

<sup>5</sup> Wile R. Citi e-cigarettes: the e-cigarette boom is over. *Business Insider*. 15 May 2014 (<http://www.businessinsider.com/citi-e-cigarette-growth-slows-2014-5>).

<sup>6</sup> Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

<sup>7</sup> Attitudes of Europeans towards tobacco (Special Eurobarometer 385). European Commission, May 2012.

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America had tried e-cigarettes, but prevalence of established use was 4% in this group.<sup>1</sup> Users report that the main reasons for using ENDS are to reduce or stop smoking and because they can be used in smoke-free places.<sup>2</sup>

9. According to the recent WHO survey, ENDS availability is widespread. Slightly over half of the world's population live in 62 countries that report the availability of ENDS in their jurisdictions, 4% live in countries reporting that ENDS are not available, while the rest live in countries that did not respond concerning the availability of ENDS.

10. Recently, the transnational tobacco companies have entered the ENDS market. Some of them are aggressively competing with the independent companies to gain market share. Given the economic power of the tobacco industry, recent moves to sue other companies alleging patent infringement may be an indicator of how difficult it will be for ENDS to remain a business niche dominated by independent companies.

#### QUESTIONS RELATED THE USE OF ENDS

11. Questions have been articulated in three groups:

- (a) health risks to users and non-users;
- (b) efficacy in helping smokers to quit smoking and ultimately nicotine dependence; and
- (c) interference with existing tobacco-control efforts and implementation of the WHO FCTC.

#### Health risks to users and non-users

12. Most ENDS products have not been tested by independent scientists but the limited testing has revealed wide variations in the nature of the toxicity of contents and emissions.

13. Health risks from nicotine inhalation are affected by several factors.

- (a) The capacity of ENDS to deliver nicotine to the user varies widely, ranging from very low to levels similar to that of cigarettes, depending on product characteristics, user puffing behaviour and nicotine solution concentration.
- (b) Nicotine is the addictive component of tobacco. It can have adverse effects during pregnancy and may contribute to cardiovascular disease. Although nicotine itself is not a carcinogen, it may function as a "tumour promoter".<sup>3</sup> Nicotine seems involved in fundamental aspects of the biology of malignant diseases, as well as of neurodegeneration.

<sup>1</sup> Giovenco DP, Lewis MJ, Delnevo CD. Factors associated with e-cigarette use. American Journal of Preventive Medicine. Published online, 27 May 2014. doi: <http://dx.doi.org/10.1016/j.amepre.2014.04.009>.

<sup>2</sup> Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. Circulation. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

<sup>3</sup> Nicotine alters essential biological processes like regulation of cell proliferation, apoptosis, migration, invasion, angiogenesis, inflammation and cell-mediated immunity in a wide variety of cells including fetal, embryonic and adult stem cells, adult tissues as well as cancer cells.



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(c) The evidence is sufficient to caution children and adolescents, pregnant women, and women of reproductive age about ENDS use because of the potential for fetal and adolescent nicotine exposure to have long-term consequences for brain development.<sup>1</sup>

14. The main health risk from nicotine exposure other than through inhalation is nicotine overdose by ingestion or through dermal contact. Since most countries do not monitor these incidents the information is very scarce. Reports from the United States and the United Kingdom nonetheless indicate that the number of reported incidents involving nicotine poisoning has risen substantially as the use of ENDS has increased. The actual number of cases is probably much higher than those reported.

15. Evidence concerning the health risks resulting from chronic inhalation of toxicants in aerosol to ENDS users are described below.

(a) Short-term effects of ENDS use include eye and respiratory irritation caused by exposure to propylene glycol. Serious short-term health problems may occur but are very rare.

(b) Given the relatively recent entry of ENDS into the market and the lengthy lag time for onset of many diseases of interest,<sup>2</sup> such as cancer, conclusive evidence about the association of ENDS use with such diseases will not be available for years or even decades.

(c) However, evidence based on the assessment of the chemical compounds in the liquids used in and aerosol produced by ENDS indicate:

- (i) potential cytotoxicity of some solutions that have raised concerns about pregnant women who use ENDS or are exposed to second-hand ENDS aerosol.<sup>3</sup> Cytotoxicity was related to the concentration and number of flavourings used in the e-liquid;
- (ii) the aerosol usually contains some carcinogenic compounds and other toxicants found in tobacco smoke at average levels of 1–2 orders of magnitude lower than in tobacco smoke, but higher than in a nicotine inhaler. For some brands, the level of some of these cancer causing agents, such as formaldehyde and other toxicants like acrolein have been found to be as high as in the smoke produced by some cigarettes;<sup>4</sup>
- (iii) the range of size of particles delivered by ENDS is similar to that of conventional cigarettes, with most particles in the ultrafine range (modes around 100–200 nm) compared to the bigger size found in cigarette smoke. However, ENDS generate lower level of particles than cigarettes.<sup>5</sup>

(d) Therefore, it is very likely that average ENDS use produces lower exposures to toxicants than combustible products.

16. Evidence concerning the health risks resulting from inhalation of second-hand ENDS aerosol by non-users are described below.

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<sup>1</sup> The health consequences of smoking – 50 years of progress. A report of the Surgeon General. Rockville (MD): US Department of Health and Human Services: 2014 (p.126).

<sup>2</sup> Including the lack of agreed early biomarker changes to assess potential harms.

<sup>3</sup> Bahl V, Lin S, Xu N, Davis B, Wang Y. Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. *Reproductive Toxicology*. 2012;34:529–37.

<sup>4</sup> Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control*. 2014;23(2):133–139. doi:10.1136/tobaccocontrol-2012-050859.

<sup>5</sup> Schripp T., D. Markewitz, E. Uhde, and T. Salthammer. Does e-cigarette consumption cause passive vaping? *Indoor Air*. 2013;23(1):25–31.

(a) Bystanders are exposed to the aerosol exhaled by ENDS users, which increases the background level of some toxicants,<sup>1,2</sup> nicotine<sup>3</sup> as well as fine and ultrafine particles in the air. Nevertheless the level of toxicants, nicotine and particles emitted from one ENDS is lower than that of conventional cigarette emissions.<sup>4</sup> It is not clear if these lower levels in exhaled aerosol translate into lower exposure, as demonstrated in the case of nicotine. Despite having a lower levels of nicotine than in second-hand smoke, the exhaled ENDS aerosol results in similar uptake as shown by similar serum cotinine levels.<sup>5</sup>

(b) It is unknown if the increased exposure to toxicants and particles in exhaled aerosol will lead to an increased risk of disease and death among bystanders as does the exposure to tobacco smoke. However, epidemiological evidence from environmental studies shows adverse effects of particulate matter from any source following both short-term and long-term exposures. The low end of the range of concentrations at which adverse health effects has been demonstrated is not greatly above the background concentration, which for particles smaller than 2.5 µm has been estimated to be 3–5 µg/m<sup>3</sup> and increases with dose, which means that there is no threshold for harm and that public health measures should aim at achieving the lowest concentrations possible.<sup>6</sup>

17. In summary, the existing evidence shows that ENDS aerosol is not merely “water vapour” as is often claimed in the marketing for these products. ENDS use poses serious threats to adolescents and fetuses. In addition, it increases exposure of non-smokers and bystanders to nicotine and a number of toxicants. Nevertheless, the reduced exposure to toxicants of well-regulated ENDS used by established adult smokers as a complete substitution for cigarettes is likely to be less toxic for the smoker than conventional cigarettes or other combusted tobacco products. The amount of risk reduction, however, is presently unknown. The 2014 Surgeon General’s Report concluded that non-combustible products such as ENDS are much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced.

#### **Efficacy in helping smokers to quit smoking and ultimately nicotine dependence**

18. Although anecdotal reports indicate that an undetermined proportion of ENDS users have quit smoking using these products their efficacy has not been systematically evaluated yet. Only a few studies have examined whether the use of ENDS is an effective method for quitting tobacco smoking.

<sup>1</sup> Under near real-use conditions, e-cigarettes increased indoor air levels of polycyclic aromatic hydrocarbons, 1,2-propanediol, 1,2,3-propanetriol, glycerine, and aluminium.

<sup>2</sup> Schober W, Szendrei K, Matzen W, Osiander-Fuchs H, Heitmann D, Schettgen T et al. Use of electronic cigarettes (e-cigarettes) impairs indoor air quality and increases FeNO levels of e-cigarette consumers. *International Journal of Hygiene and Environmental Health*. 2014;217(6):628–37. doi:10.1016/j.ijheh.2013.11.003.

<sup>3</sup> Czogala J1, Goniewicz ML, Fidelus B, Zielinska-Danch W, Travers MJ, Sobczak A. Secondhand exposure to vapors from electronic cigarettes. *Nicotine and Tobacco Research*. 2014;16(6):655–62. doi: 10.1093/ntr/ntt203.

<sup>4</sup> McAuley TR, Hopke PK, Zhao J, Babaian S. Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhalation Toxicology*. 2012;24(12):850-7.

<sup>5</sup> Flouris AD, Chorti MS, Poulitani KP, Jamurtas AZ, Kostikas K, Tzatzarakis MN et al. Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function. *Inhalation Toxicology*. 2013;25(2):91–101. doi: 10.3109/08958378.2012.758197.

<sup>6</sup> WHO air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide: summary of risk assessment. Geneva: World Health Organization; 2006.

<sup>7</sup> The health consequences of smoking – 50 years of progress: a report of the Surgeon General. Atlanta (GA): US Department of Health and Human Services; 2014 (p. 874).



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19. The evidence for the effectiveness of ENDS as a method for quitting tobacco smoking is limited and does not allow conclusions to be reached. However, the results of the only randomized control trial that compared use of ENDS, with or without nicotine, to use of nicotine patches without medical assistance in the general population, showed similar, although low, efficacy for quitting smoking.<sup>1</sup> A recent study also shows some, although limited, effectiveness in real-world conditions.<sup>2</sup>

20. At this level of efficacy, the use of ENDS is likely to help some smokers to switch completely from cigarettes to ENDS. However, for a sizeable number of smokers ENDS use will result in the reduction of cigarette use rather than in quitting. This will lead to dual use of ENDS and cigarettes. Given the likely greater importance of duration of smoking (number of years smoking) over intensity (number of cigarettes smoked per day) in generating negative health consequences, dual use will have much smaller beneficial effects on overall survival compared with quitting smoking completely.<sup>3</sup>

21. No ENDS product has yet been evaluated and approved for smoking cessation by a governmental agency, although the United Kingdom's Medicines and Healthcare Products Regulatory Agency is in the process of reviewing some of these products.

22. In considering ENDS as a potential cessation aid, smokers should first be encouraged to quit smoking and nicotine addiction using a combination of already approved treatments. However, at the individual level, experts suggest that in some smokers who have failed treatment, have been intolerant to it or who refuse to use conventional smoking cessation medication, the use of appropriately-regulated ENDS may have a role to play in supporting attempts to quit.<sup>4,5</sup>

**Impact on existing tobacco-control efforts**

23. Although ENDS present a range of potential benefits to smokers, there is an extensive and often heated debate about whether ENDS will prove to have a positive or negative impact on population health and particularly tobacco control. Areas of legitimate concern include avoiding nicotine initiation among non-smokers and particularly youth while maximizing potential benefits for smokers. Such concerns are referred to as the gateway and renormalization effects.

24. Gateway and renormalization concerns.

- (a) The gateway effect refers to two potential circumstances:
  - (i) the possibility that children (and generally non-smokers) will initiate nicotine use with ENDS at a rate greater than expected if ENDS did not exist,<sup>6</sup> and
  - (ii) the possibility that once addicted to nicotine through ENDS children will switch to cigarette smoking.

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<sup>1</sup> Bullen CB, Howe C, Laugesen M, McRobbie H, Parag V, Williman J et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*. 2013;382(9905):1629–37.

<sup>2</sup> Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction*. Published online, 20 May 2014. doi:10.1111/add.12623.

<sup>3</sup> The health consequences of smoking – 50 years of progress: a report of the Surgeon General. Atlanta (GA): US Department of Health and Human Services; 2014.

<sup>4</sup> Fiore MC, Schroeder SA, Baker TB. Smoke, the chief killer – strategies for targeting combustible tobacco use. *New England Journal of Medicine*. 2014;370(4):297–9. doi: 10.1056/NEJMp1314942.

<sup>5</sup> Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

<sup>6</sup> this This does not mean that use of ENDS by children is not a concern in itself.



(b) The renormalization effect refers to the possibility that everything that makes ENDS attractive to smokers may enhance the attractiveness of smoking itself and perpetuate the smoking epidemic. ENDS mimic the personal experience and public performance of smoking and their market growth requires marketing that is challenging commercial communication barriers erected to prevent the promotion of tobacco products.

(c) The likelihood and significance of these two effects occurring will be the result of a complex interplay of individual, market and regulatory factors and is difficult to predict. They can only be assessed with empirical data, which at present are virtually non-existent.

(d) The limited existing survey data from a handful of countries show that experimentation with ENDS is increasing rapidly among adolescents and that in itself is of great concern even if most of the young ENDS users also smoke. In fact, except in one case, the surveys show that there are few exclusive ENDS users who have never smoked (mostly around 1% of the population).<sup>1,2,3</sup> These data do not allow the conclusions to be drawn as to whether this is a sign of adolescent smokers switching to ENDS, an established pattern of dual use, or a temporary experimentation fashion. Therefore, in the absence of longitudinal data, existing evidence does not allow an affirmation or rejection of the role of ENDS in increasing nicotine addiction among adolescents above existing uptake rates, much less as to whether ENDS lead to smoking in these countries. Among adults the pattern of dual use seems also the predominant one, resulting in a reduction of smoked cigarettes and with few never smokers starting to use ENDS (below 1% of the population).<sup>4,5</sup>

(e) There are also very limited data from very few countries about the evolution of the smoking epidemic in the presence of the ENDS boom. In one country (United Kingdom), where tobacco-control measures are very strong and ENDS use is popular and growing, it seems that smoking prevalence, cigarette consumption as well as overall nicotine use continues to decrease gradually.<sup>6</sup> Whether these contrasting trends are causally related cannot be concluded from these data. At least for the United Kingdom, renormalization as measured by prevalence of smoking is not occurring currently. Whether this would be the case for other countries cannot be generalized from the existing data and needs to be proven empirically.

25. More specific public health questions related to the interaction between ENDS and tobacco-control efforts are discussed below.

26. Positioning the tobacco-control message: The entry of ENDS in the market has created challenges to the core message of tobacco control, which until now has been that tobacco use should

<sup>1</sup> Calculations based on Centers for Disease Control and Prevention reported data from the United States National Youth Tobacco Survey, contained in: Corey C, Wang B, Johnson SE, Apelberg B, Husten C, King BA et al. Notes from the field: electronic cigarette use among middle and high school students – United States, 2011–2012. *Morbidity and Mortality Weekly Report*;62(35):729–30.

<sup>2</sup> Lee S, Grana RA, Glantz SA. Electronic cigarette use among Korean adolescents: a cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking. *Journal of Adolescent Health*. Published online, 22 November 2013. doi: <http://dx.doi.org/10.1016/j.jadohealth.2013.11.003>.

<sup>3</sup> Lukasz Goniewicz M, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. *Pediatrics*. Published online, 17 September 2012. doi:10.1542/peds.2011-3448.

<sup>4</sup> Sutfin EL, McCoy TP, Morrell HER, Hoepfner BB, Wolfson M. Electronic cigarette use by college students. *Drug and Alcohol Dependence*. 2013;131(3):214–221. <http://dx.doi.org/10.1016/j.drugalcdep.2013.05.001>.

<sup>5</sup> ASH UK fact sheet. Use of electronic cigarettes in Great Britain. April 2014. Available from: [http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf).

<sup>6</sup> West R, Brown J, Beard E. Smoking toolkit study. Trends in electronic cigarette use in England. Updated 4th April 2014. Available from: <http://www.smokinginengland.info/latest-statistics/>.



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not be started and if started it should be stopped.<sup>1</sup> The promotion of ENDS comes with at least one of the following messages or a combination of them: (a) try to quit smoking and if everything fails use ENDS as the last resort; (b) you do not need to quit nicotine addiction, just smoking; and (c) you do not need to quit smoking, use ENDS where you cannot smoke. Some of these messages are difficult to harmonize with the core tobacco-control message and others are simply incompatible.

27. The role of the tobacco industry: The future role of ENDS is strongly determined by the commercial interests of the industry that manufactures and sells ENDS. While there are "independent" ENDS companies that have reported no interest in perpetuating tobacco use, the tobacco industry involved in the production and sale of ENDS certainly is.

(a) The ENDS market, initially dominated by companies with no links to the tobacco industry, is increasingly owned by the tobacco industry. All main transnational tobacco companies sell ENDS and one of them is launching legal proceedings over patents against its rivals as they become increasingly aggressive in the battle for the fast-growing e-cigarette market. The increasing concentration of the ENDS market in the hands of the transnational tobacco companies is of grave concern in light of the history of the corporations that dominate that industry.

(b) It is unclear yet what this means for the ENDS market. However, if prior interest of the tobacco industry in reduced-risk products serves as a precedent, their interest lies in maintaining the status quo in favour of cigarettes for as long as possible, while simultaneously providing a longer-term source of profit should the cigarette model prove unsustainable. In addition, selling these products is intended to bring reputational benefits to these companies, as they can pretend to be part of the solution to the smoking epidemic.<sup>2</sup> ENDS may follow the trend of smokeless tobacco wherein the industry's historic interest in smokeless tobacco products outside some Nordic countries was both because they could be used in smoke-free environments and because they could be promoted to young, non-tobacco users to create a new form of tobacco use.<sup>3</sup>

28. Potential interference with smoke-free policies.

(a) Smoke-free policies are designed not only to protect non-smokers from second-hand smoke, but also to provide incentives to quit smoking and to denormalize smoking as adolescents are particularly vulnerable to visual cues and social norms.<sup>4</sup>

(b) The use of ENDS in places where smoking is not allowed

- (i) increases the exposure to exhaled aerosol toxicants of potential harm to bystanders,
- (ii) reduces quitting incentives, and
- (iii) may conflict with the smoking denormalizing effect.

(c) Many ENDS look like smoking products and even if they do not resemble them, the exhaled vapour looks like tobacco smoke. ENDS are marketed to be used where smoking is

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<sup>1</sup> de Andrade M, Hastings G, Angus K, Dixon D, Purves R. The marketing of electronic cigarettes in the UK. London: Cancer Research UK; November 2013.

<sup>2</sup> Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. Tobacco Control. Published online, 22 January 2014. doi:10.1136/tobaccocontrol-2013-051502.

<sup>3</sup> Mejia AB, Ling PM. Tobacco industry consumer research on smokeless tobacco users and product development. American Journal of Public Health. 2010;100(1):78–87. doi: 10.2105/AJPH.2008.152603.

<sup>4</sup> Preventing tobacco use among youth and young adults. A report of the Surgeon General. Rockville (MD): US Department of Health and Human Services; 2012.



prohibited and given the resemblance to tobacco products it is likely that their use where smoking is banned will make enforcing smoke-free policies more difficult.

(d) The fact that ENDS exhaled aerosol contains on average lower levels of toxicants than the emissions from combusted tobacco does not mean that these levels are acceptable to involuntarily exposed bystanders. In fact, exhaled aerosol is likely to increase above background levels the risk of disease to bystanders, especially in the case of some ENDS that produce toxicant levels in the range of that produced by some cigarettes.

29. The role of ENDS marketing (which falls into two categories: consumer marketing aimed at the general public, and stakeholder marketing aimed at policy-makers and public health bodies):

(a) ENDS are being marketed to consumers in many media and forms, including television commercials, sports and cultural sponsorship, celebrity endorsement, social networking, online advertising, point-of-sale displays, pricing strategies, and product innovation. Some marketing clearly emulates the very successful tobacco advertising asserting an independent identity and a lifestyle choice, aligning oneself with celebrities, fashionable and youthful places and activities. Some ENDS are marketed not only as socially acceptable but as socially superior. Unsubstantiated or overstated claims of safety and cessation are frequent marketing themes aimed at smokers. Some ENDS marketing also promotes long-term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned. ENDS marketing activities have the potential to glamorize smoking and attracting children and non-smokers even if those are unintentional results. However, no empirical studies have been conducted to show whether the negative prospects of ENDS marketing are actually directly associated with attitudinal and behavioural changes among children and non-smokers consistent with the realization of such potential. Concerns have also been raised over the use of flavours in the marketing of ENDS. One recent study indicates that ENDS are marketed in 7764 unique flavours.<sup>3</sup> Although the role of ENDS flavours potential attractiveness has not been studied yet, expert opinion indicates that candy-like flavours could entice youths to experiment with ENDS and could also facilitate the development of tobacco dependence by enhancing the sensory rewards of ENDS use.<sup>1</sup> The tobacco industry's internal documents suggest that flavouring agents have played an important role in the industry's targeting of children and youth, and there is a concern that they could play the same role in the uptake of ENDS in these age groups.

(b) The marketing message to tobacco-control stakeholders is one of alignment of industry and public health interests based on the harm reduction potential of ENDS. This leads to a proposal of partnership between government and industry because industry claims a meaningful seat at the table in the so-called harm reduction debate.

#### CURRENT REGULATION AND POLICY: RESULTS OF THE WHO SURVEY

30. Table 1 reflects the results of the 2014 WHO survey, showing the distribution of countries according to the regulatory approach taken to ENDS.

Type of ENDS	ENDS regulated as					Not regulated or unknown
	consumer product	therapeutic product	tobacco product	other	total	
With nicotine	14 (27%)*	12 (6%)	22 (10%)	11 (6%)	59 (49%)	135 (51%)
Without nicotine	23 (35%)	0 (0%)	18 (7%)	12 (2%)	53 (44%)	141 (56%)

<sup>1</sup> The scientific basis of tobacco product regulation: a WHO Study Group on Tobacco Product Regulation report. Candy-flavoured tobacco products: research needs and regulatory recommendations. Geneva; World Health Organization: 2007 (WHO Technical Report Series 945).

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\* The figure in parentheses after the number of countries indicates the percentage of the world population living in these countries.

31. The sale of ENDS with nicotine is banned in 13 of the 59 countries that regulate them. However, the majority of these 13 countries report that ENDS are available to the public, probably through illicit trade and cross-border Internet sales.

32. The survey also shows that:

- (a) comprehensive advertising, promotion and sponsorship bans on ENDS are in place in 39 countries (in which 31% of the world's population live);
- (b) use of ENDS in enclosed public places is banned in 30 countries (35%);
- (c) premarket review is required by 19 countries (5%);
- (d) vendor licences are required by nine countries (4%);
- (e) policies on ENDS sales to minors were confirmed by 29 countries (8%). Where specified, minimum required age for purchase ranged from 18 to 21 years.

**GENERAL CONSIDERATIONS**

33. Smokers will obtain the maximum health benefit if they completely quit both tobacco and nicotine use. In fact, Article 5.2(b) of the Convention commits Parties not only to preventing and reducing tobacco consumption and exposure to tobacco smoke but also to preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not.

34. The rapid growth of ENDS use globally can neither be dismissed nor accepted without efforts to appropriately regulate these products, so as to minimize consequences that may contribute to the tobacco epidemic and to optimize the potential benefits to public health. Thus it is important to identify public health concerns and to consider these concerns when undertaking regulation and surveillance.

35. Regulation of ENDS is a necessary precondition for establishing a scientific basis on which to judge the effects of their use, and for ensuring that adequate research is conducted, that the public has current, reliable information as to the potential risks and benefits of ENDS, and that the health of the public is protected. Public health authorities need to prioritize research and invest adequately to elucidate evidentiary uncertainties as soon as possible. However, the greater responsibility to prove claims about ENDS scientifically should remain with the industry.

36. When designing a regulatory strategy for ENDS, governments should bear in mind the following general regulatory objectives:

- (a) impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;
- (b) minimize potential health risks to ENDS users and non-users;
- (c) prohibit unproven health claims from being made about ENDS; and
- (d) protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.

37. Because the product, the market and the associated scientific evidence surrounding ENDS are all evolving rapidly, all legislation and regulations related to ENDS should be adaptable in response to



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new scientific evidence, including evaluation of different models for ENDS regulation, as evidence accumulates.

38. Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of ENDS will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realized.

#### **SPECIFIC REGULATORY OPTIONS**

39. In order to achieve the general regulatory objectives mentioned above, Parties that have not banned the sale of ENDS could consider the following non-exhaustive list of regulatory options, on the understanding that the advisability and feasibility at country level of each of these options will depend on a complex set of country-specific factors, including the existing regulatory frameworks and the legal exigencies of the regulatory process.

40. **Health claims.** Prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids, until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval. The regulatory standard for cessation claims and approval as cessation aids should remain an appropriate body of evidence, based on well-controlled clinical trials. For ENDS products to be approved for smoking cessation by the suitable regulatory agency, the appropriate balance should be reached between providing accurate scientific information to the public about the risks of ENDS use and its potential benefits as compared with smoking. This balance can only be determined through scientifically tested audience messaging.

41. **Use of ENDS in public places.** Since the reasonable expectation of bystanders is not a diminished risk in comparison to exposure to second-hand smoke but no risk increase from any product in the air they breathe, ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapour is proven to be not harmful to bystanders and reasonable evidence exists that smoke-free policy enforcement is not undermined. If smoke-free legislation is not fully developed according to Article 8 of the WHO FCTC and the guidelines for its implementation, this should be done as soon as possible.

42. **Advertising, promotion and sponsorship.** Given that the same promotional elements that make ENDS attractive to adult smokers could also make them attractive to children and non-smokers, Parties should contemplate putting in place an effective restriction on ENDS advertising, promotion and sponsorship. Some forms of ENDS promotion, however, may be considered acceptable by Parties if empirical evidence shows that ENDS might play a role in helping some smokers to quit without leading to increased ENDS use by minors and non-smokers who otherwise would not have used nicotine.

43. Any form of ENDS advertising, promotion and sponsorship must be regulated by an appropriate governmental body. If this is not possible, an outright ban on ENDS advertising, promotion and sponsorship is preferable to the implementation of voluntary codes on ENDS marketing, given the overwhelming evidence that similar codes for tobacco and alcohol products have failed to protect young people from such advertising.

44. Advertising, promotion and sponsorship of ENDS with or without nicotine, must, at a minimum:

- (a) state clearly whether the product contains nicotine or may be used with nicotine solutions;
- (b) not make them appealing to or target, either explicitly or implicitly, non-smokers or non-nicotine users, and must therefore indicate that ENDS are not suitable for use by people who do not currently consume tobacco products;

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- (c) not make them appealing to or target, either explicitly or implicitly, minors, including through the selection of media, location or the context in which they appear or through imagery that promotes sexual or sporting prowess;
  - (d) never promote ENDS for non-smokers, and their use should not be portrayed as a desirable activity in its own right;
  - (e) encourage smoking cessation and provide a quitline number if one exists;
  - (f) contain nothing that could reasonably be expected to promote the use of tobacco products, such as:
    - (i) the appearance or/and use of tobacco products;
    - (ii) the use of any brand name, design, colour, emblem, trademark, logo or trade insignia or any other distinctive feature that might be associated by the audience with a tobacco product;
    - (iii) the use of the words e-cigarette, electronic cigarette, or any other descriptor that might reasonably be expected to create confusion with the promotion of cigarettes and other combustible tobacco products;
    - (iv) showing ENDS products in ways that could reasonably be expected to promote tobacco products, including images of tobacco-like products;
  - (g) not contain health or medicinal claims, unless the product is licensed for those purposes by the appropriate regulatory agency. Electronic cigarettes and other nicotine-containing products should be presented only as an alternative to tobacco, and should include warnings that dual use will not substantially reduce the dangers of smoking;
  - (h) not undermine any tobacco-control measure, including by not promoting the use of ENDS in places where smoking is banned;
  - (i) include factual information about product ingredients other than nicotine and in a way that does not distort evidence of risks;
  - (j) not link these products with gambling, alcohol, illicit drugs or with activities or locations in which using them would be unsafe or unwise.
45. Advertising, promotion and sponsorship of ENDS that contain nicotine or may be used with nicotine solutions must:
- (a) clearly state the addictive nature of nicotine and that these products are intended to deliver nicotine;
  - (b) Prohibit suggestions that ENDS have positive qualities as a consequence of the addictive nature of the product.
46. All authorized forms of ENDS advertising, promotion and sponsorship must be cleared by the appropriate authority prior to publication/transmission in order to proactively prevent inappropriate marketing, and then be monitored to assess compliance.
47. **Protection from vested commercial interests.** Transparency should be required from ENDS and tobacco companies advocating for and against legislation and regulation, both directly and through third parties. No matter what role the tobacco industry plays in the production, distribution and sale of ENDS, this industry, its allies and front-groups can never be considered to be a legitimate public health partner or stakeholder while it continues to profit from tobacco and its products or represents the interests of the industry. Article 5.3 of the WHO FCTC should be respected when developing and implementing ENDS legislation and regulations.



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48. **Product design and information.** ENDS should be regulated to:
- (a) minimize content and emissions of toxicants;
  - (b) ensure use of nicotine of pharmacological quality, when nicotine use is intended;
  - (c) standardize nicotine delivery at levels known to the consumers;
  - (d) minimize acute nicotine toxicity;
  - (e) impede product alteration to use of other drugs;
  - (f) ban ENDS solutions with fruit, candy-like and alcohol-drinks flavours until empirical evidence shows that they are not attractive to minors;
  - (g) require manufacturers and importers to disclose to governmental authorities information about the contents and emissions of ENDS; and
  - (h) require registration of manufacturers and importers with governmental authorities.
49. **Health warnings.** ENDS health warnings should be commensurate with proven health risks. In this regard, the following risk warnings could be considered: potential nicotine addiction; potential respiratory, eyes, nose and throat irritant effect; potential adverse effect on pregnancy (due to nicotine exposure).
50. **Surveillance and monitoring.** Governments are recommended to use or strengthen their existing tobacco surveillance and monitoring systems to assess developments in ENDS and nicotine use by sex and age.
51. **Sale to minors.** Retailers should be prohibited from selling ENDS products to minors, and vending machines should be eliminated in almost all locations.

#### **REGULATORY FRAMEWORK**

52. In order to implement the suggested general regulatory objectives as well as the specific regulatory options, Parties will need to consider the available national regulatory frameworks that could best provide solid regulatory grounds. Nevertheless, it is likely that a two-pronged regulatory strategy – regulating ENDS as both a tobacco product, in accordance with the provisions of the WHO FCTC, and as a medical product – would be necessary.

53. The applicability of many of the WHO FCTC provisions to the regulation of ENDS was reviewed in a report by the Convention Secretariat on this topic<sup>1</sup> presented at the fifth session of the COP.

#### **ACTION BY THE CONFERENCE OF THE PARTIES**

54. The COP is invited to note this report and to provide further guidance.

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<sup>1</sup> Document FCTC/COP/5/13 (available at [www.who.int/fctc/publications](http://www.who.int/fctc/publications)).



## Bilag 2 – Four hundred and sixty brands of e-cigarettes and counting

Original article



### Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation

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#### ABSTRACT

**Introduction** E-cigarettes are largely unregulated and internet sales are substantial. This study examines how the online market for e-cigarettes has changed over time: in product design and in marketing messages appearing on websites.

**Methods** Comprehensive internet searches of English-language websites from May–August 2012 and December 2013–January 2014 identified brands, models, flavours, nicotine strengths, ingredients and product claims. Brands were divided into older and newer groups (by the two searches) for comparison.

**Results** By January 2014 there were 466 brands (each with its own website) and 7764 unique flavours. In the 17 months between the searches, there was a net increase of 10.5 brands and 242 new flavours per month. Older brands were more likely than newer brands to offer cigalikes (86.9% vs 52.1%,  $p<0.01$ ), and newer brands more likely to offer the more versatile eGos and mods (75.3% vs 57.8%,  $p<0.01$ ). Older brands were significantly more likely to claim that they were healthier and cheaper than cigarettes, were good substitutes where smoking was banned and were effective smoking cessation aids. Newer brands offered more flavours per brand (49 vs 32,  $p<0.01$ ) and were less likely to compare themselves with conventional cigarettes.

**Conclusions** The number of e-cigarette brands is large and has been increasing. Older brands tend to highlight their advantages over conventional cigarettes while newer brands emphasise consumer choice in multiple flavours and product versatility. These results can serve as a benchmark for future research on the impact of upcoming regulations on product design and advertising messages of e-cigarettes.

#### INTRODUCTION

Electronic cigarettes (e-cigarettes) are battery-powered nicotine delivery systems. They come in many varieties but can generally be grouped into three categories: cigalikes, which are models resembling conventional cigarettes in shape and size; eGos, which are larger than cigalikes, usually with a removable 'tank' that can be refilled with nicotine-containing e-liquid; and mods, which are usually larger than eGos and almost endlessly customisable.<sup>1</sup>

E-cigarettes have generated considerable interest among potential consumers.<sup>2–6</sup> Even before they had been promoted through large-scale television advertising, more than two-thirds of US adults, smokers and non-smokers, had heard of e-cigarettes.<sup>7</sup> The use of e-cigarettes is increasing among adults and youth.<sup>6–9</sup> Anticipating the market opportunities, Lorillard, a large American

tobacco company, acquired a major e-cigarette brand, blu eCigs, in April 2013.<sup>10</sup> This acquisition also initiated national paid advertising campaigns to promote e-cigarettes.<sup>11–12</sup> Other tobacco companies quickly followed. Altria purchased the brand Green Smoke in 2014 and RJ Reynolds plans to begin selling its own VUSE brand nationally.<sup>13–14</sup> NJOY, the most well-known brand not owned by a tobacco company, has also conducted major advertising campaigns to tout the relative advantage of e-cigarettes over conventional cigarettes.<sup>15–17</sup>

E-cigarettes are mostly unregulated. Some countries have imposed restrictions on the sale of certain types of e-cigarettes,<sup>18</sup> but the availability of e-cigarettes in all varieties on the internet has made enforcement difficult. As this paper was going through editorial revision, the US Food and Drug Administration (FDA) proposed to deem e-cigarettes as a tobacco product.<sup>19</sup> The proposed rules will ban selling e-cigarettes to minors. It will not, however, ban internet sales. At this point, the e-cigarette market shows every sign of growing. In the USA alone, it is projected to reach \$2 billion in 2014.<sup>20–21</sup>

A significant portion of e-cigarette business is conducted on the internet, although it is difficult to ascertain the exact volume. Several sources estimate that it is about 30–50% of total e-cigarettes sold.<sup>22–23</sup> There are reasons for the active internet market: It is relatively easy to set up a new e-cigarette company online, with small financial investment. No large advertising budget is required to achieve a web presence. In addition, most existing e-cigarette companies have their own websites and most of them also sell e-cigarettes over the internet. Thus, the internet reflects the majority of the e-cigarette market when it comes to issues such as the number of brands available for consumers.

This paper examines e-cigarette brands that are advertised and sold on the internet. It is an update of our report on an internet search of e-cigarette brands in 2012, which found more than 250 brands available at the time.<sup>24</sup> This updated internet search, it should be noted, was finished 3 months before the US FDA issued its deeming proposal.<sup>19</sup>

The present study has two related aims. First, it provides a basic description of how e-cigarette brands have presented themselves: what is being offered to consumers and what claims are made about any presumed advantages over cigarettes. Second, it compares the brands that were sold on the internet in 2012 with those that became available since then (up to January 2014). It was expected that many new brands would appear on



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the internet. Given that e-cigarettes have been largely unregulated so far, it would be interesting to examine how new brands compete with older, more established brands. By studying the changes taking place in an unregulated marketplace, useful insights might be gained to inform future regulatory policies.

### METHODS

#### Search methods

Two comprehensive searches of e-cigarette brands found on the internet were conducted: the first from May 2012 to August 2012, and the second from December 2013 to January 2014. We used three search engines: Google, Yahoo and Bing, and 13 keywords: 'e-cigarette,' 'e cigarette,' 'e-cig,' 'e cig,' 'ecig,' 'ecigs,' 'electronic cigarette,' 'electronic cig,' 'electronic nicotine delivery system,' 'vape,' 'vaper' and 'vaping.' The first 30 pages of each search were reviewed to capture any possible e-cigarette brand websites.

Non-English websites, sites that did not sell products directly to consumers (wholesale sites, manufacturer sites, product review sites) and resale sites such as eBay and Amazon were excluded. Also excluded were websites that did not offer online sales, even if their products were available to view on their website (eg, MarkTen and VUSE), and sites that only sold devices used predominantly for marijuana or other substances. The first search was done by a project manager with three research assistants. The project manager created the database, trained research assistants and supervised the coding process. The second search was done by a project manager with 14 research assistants. During the second search, researchers also revisited the websites of all brands found during the first search. For the second search, a new codebook was created with detailed instructions on how to identify brands, products and models, product claims, nicotine strengths, flavours and ingredients. The project manager performed daily quality assurance checks to ensure consistency and was available at all times during data collection to resolve any discrepancies or questions. All data analysis in this study was based on results from the second search. The only data used from the first search were the brand names found in 2012.

### Measures

#### Brands

A website was coded as carrying a brand if it identified at least one e-cigarette-related product (such as a cigalike, cartridge, atomiser or e-liquid) as its own through a distinct name or logo. Sites that sold only e-liquid but no e-cigarette hardware were not considered to have a brand and were excluded. Websites that, in addition to selling their own brand also sold other brands, were counted as having one brand. Thus, one site, one brand.

#### Types and models

There are three basic types of e-cigarettes: cigalikes, eGos and mods. A website could offer different models within each type. For example, a website might offer the eGo and the eGo VV. They would be counted as two different models of eGo. If products only varied in colour or flavour of e-liquid, then they were not counted as separate models.

Some e-cigarette sites also sold e-hookah (an electronic version of the traditional hookah), and e-cigars or e-pipes (electronic versions with a similar shape to traditional cigars or pipes). They were recorded separately and were included as different models.

### Flavours

Every flavour available from each site was recorded, and the individual names were the focus of the analysis. In addition, each flavour was coded into one of eight categories, including Tobacco, Menthol, Tobacco-Menthol, Fruit, Dessert/Candy, Alcohol/Drinks, Snacks/Meals and Others. When relevant, flavours were coded by first ingredient. Flavours that referenced tobacco brands were coded as tobacco. Flavours described as minty, icy or frosty were coded as menthol. Flavours like cinnamon, almonds, 'normal' and 'mystery' were coded as Other. Flavours offered on the same website with similar, but not identical, names were counted as separate flavours. Do-it-yourself flavour concentrates were excluded.

### Ingredients

A website was coded on whether it listed ingredients and, if so, how many ingredients were listed. The presence of two types of propellant, propylene glycol and vegetable glycerine, as well as the presence of water and nicotine was noted.

### Nicotine strengths

Companies reported nicotine strengths in three ways: in milligrams, percentages or using descriptors (eg, low, medium, high). There was little correspondence between descriptors and milligrams or percentage of nicotine across brands, which made standardisation infeasible. Instead, we simply counted the number of strengths. If a website reported strength information in more than one way, they were recorded as separate strengths unless the website explicitly stated that they were the same strength.

### Claims made about e-cigarettes

Claims were coded into six categories: (1) E-cigarettes are less harmful than conventional cigarettes. This includes statements such as: they are healthier, contain no carcinogens, no tar or no secondhand smoke. (2) E-cigarettes are a substitute for places where one cannot smoke. (3) E-cigarettes are cheaper than cigarettes. (4) A direct claim of e-cigarettes as an effective quitting aid. (5) An indirect claim of e-cigarettes as an effective quitting aid. An example of an indirect claim would be customer testimonials. (6) An explicit disclaimer that e-cigarettes are not approved as smoking cessation devices.

### Analysis

Brands were divided into two groups: older brands (which were active on the internet in 2012 and 2014) and newer brands (found only in 2014). Older brands were further divided into those that were well advertised and those that were not. No comprehensive study of the advertising expenditure of e-cigarette brands has been published. We used Richardson and colleagues' study, which identified five brands that were the most advertised, all of which were in the older brand group identified in this search.<sup>25</sup> The top-5 were: blu eCigs, NJOY, Green Smoke, Vapor4life and White Cloud. Logistic regression was used to assess differences in rates between old and new brands, while permutation t-tests were used to test for differences in counts of flavours and nicotine strengths. All calculations were done using R V2.15.0.<sup>26</sup>

## RESULTS

### Brands and models

The initial search in 2012 identified 288 unique e-cigarette brands. In the follow-up search 17 months later, 37 of those



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**Table 1** A comparison of products and models offered by the 466 e-cigarette brands, 2014

	Older brands* (N=251)			Older brands combined (N=251) %	Newer brandst (N=215)	
	Top-5 brands (N=5) %	Other brands (N=246) %	Top-5 vs others p value		Newer brands (N=215) %	Older vs newer brands p value
Cigalike	100.0	86.6	<0.01	86.9	52.1	<0.01
eGo	20.0	58.5	0.13	57.8	75.3	<0.01
Mod	20.0	28.0	0.71	27.9	45.1	<0.01
# of models (mean)	4.2	5.3	0.40	5.5	6.3	0.25

\*Active on the internet in 2012 and 2014.  
†Active on the internet in 2014 but not 2012.

brands were no longer active on the internet. The follow-up search identified 215 new brands. Thus, the net increase was about 10.5 brands per month. The total number of brands in January 2014 was 466 (215+288-37=466).

Table 1 shows the types of products and number of models offered by these brands. Overall, older brands were significantly more likely to offer cigalikes than newer brands (86.9% vs 52.1%). Among all older brands, the top-5 group was even more likely to offer cigalikes (100% vs 86.6%). In contrast to older brands, newer brands were more likely to offer eGos (75.3% vs 57.8%) and mods (45.1% vs 27.9%). The top-5 group was the least likely to offer either eGos or mods (20%). Only one of the top-5 brands (Vapor4Life) sold eGos and mods. The rest sold only cigalikes.

The average number of models sold per website was 5.8 with no significant difference between older and newer brands (5.5 vs 6.3). The top-5 group had even fewer models, but it was not statistically significant.

Egos and mods allow for the hardware and e-liquid to be sold separately because they are customisable and contain refillable tanks. Table 2 shows whether brands carried their own branded hardware or e-liquid. Older brands were more likely to have their own brand of hardware than newer brands (85.7% vs 64.7%) while newer brands were more likely to have own brand of e-liquid than older brands (65.6% vs 44.6%). The top-5 group always carried their own brand of hardware (100%). Among the top-5, only Vapor4Life carried its own brand of e-liquid. Blu eCigs did not sell e-liquid, though it did carry a rechargeable model and several types of prepackaged nicotine cartridges.

#### Flavours and nicotine strength

Table 3 shows the average number of flavours per brand. Newer brands had a significantly higher mean number of flavours than older ones (49 vs 32). The median was more than twice as large for the newer brands, 33 vs 15.

The total unique flavours (in the sense of unique linguistic labels for flavour) for all the brands were 7764. Of these, 4110 were offered only by newer brands and not by older ones. In other words, about 242 new flavours were added per month, on average.

Among older brands, there was no statistical difference in number of flavours offered by the top-5 brands and the rest of the older brands. However, the average masks the difference. Among the top-5 brands, only Vapor4Life offered a large number of flavours, 119. The rest offered very limited flavours, with NJOY offering only two basic flavours: tobacco and menthol.

Among all 466 brands, 93.4% offered Tobacco and 92.1% offered Menthol. Some brands (24.8%) also offered a tobacco-menthol blend. The next most popular type of flavour was Fruit, offered by 84.2% of brands, followed by Dessert/candy, 79.9%, Alcohol/drinks, 77.5%, Snacks/meals, 25.7%, and Others, 44.5% (data not shown in the table).

Table 3 also shows the number of nicotine strengths offered per brand. The mean was 4.4, with no difference between older and newer brands. It is important to note that about 83% of the brands offered zero nicotine as one option.

#### Ingredients

Overall, 75.2% of all brands listed ingredients. Table 4 shows that older brands were slightly more likely to list ingredients, but the difference was not statistically significant. All of the top-5 brands listed ingredients.

Table 4 also shows the five most commonly listed ingredients: nicotine, propylene glycol, vegetable glycerine/glycerol, flavouring and water. Older brands were more likely to list nicotine than newer brands (93.4% vs 81.7%) and less likely to list propylene glycol (84.8% vs 92.8%) or vegetable glycerine (59.9% vs 88.2%) than newer brands. Flavouring is another major category listed by older and newer brands, and older brands were more likely to list water.

**Table 2** Branded hardware or e-liquid offered by the 466 e-cigarette brands, 2014

	Older brands* (N=251)			Older brands combined (N=251) %	Newer brandst (N=215)	
	Top-5 brands (N=5) %	Other brands (N=246) %	Top-5 vs others p value		Newer brands (N=215) %	Older vs newer brands p value
Branded hardware	100.0	85.4	<0.01	85.7	64.7	<0.01
Branded e-liquid	20.0	45.1	0.28	44.6	65.6	<0.01
Branded both	20.0	37.8	0.43	37.5	38.6	0.80

\*Active on the internet in 2012 and 2014.  
†Active on the internet in 2014 but not 2012.

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**Table 3** A comparison of flavours and nicotine strengths offered by the 466 e-cigarette brands, 2014

	Older brands* (N=251)		Top-5 vs others p value	Older brands combined (N=251)	Newer brandst (N=215) Newer brands (N=215)	Older vs newer brands p value
	Top-5 brands (N=5)	Other brands (N=246)				
# of flavours per brand						
Mean	30	32	0.93	32	49	<0.01
Median	8	15.5		15	33	
# of nicotine strengths						
Mean	5.4	4.4	0.13	4.5	4.4	0.65
Median	5	4		4	5	
Zero nicotine offered	80.0%	84.1%	0.85	84.1%	81.9%	0.55

\*Active on the internet in 2012 and 2014.

†Active on the internet in 2014 but not 2012.

### Claims made about e-cigarettes

Table 5 shows the claims that brands made in reference to conventional cigarettes. Older brands were significantly more likely to claim that their products were healthier than conventional cigarettes than were newer brands (80.1% vs 59.1%). The top-5 brands were most likely to make that claim (100%). Older brands were also significantly more likely to mention that e-cigarettes could be used where conventional cigarettes are not allowed (76.5% vs 46.5%). Again, 100% of top-5 brands made that claim on their websites. Older brands were also more likely to claim that their products were cheaper than conventional cigarettes (70.1% vs 47.0%). Once again, all top-5 brands made that claim. Finally, older brands were more likely than newer brands to indirectly claim that their products are effective for smoking cessation (principally through testimonials), 60.6% vs 48.4%, with no difference between the top-5 brands and the other older brands. Moreover, 11.6% of newer brands and 10% of older brands made a direct claim about the efficacy of e-cigarettes to help smokers quit cigarettes, which was not statistically different. In contrast, none of the top-5 brands made such a direct claim. Older brands were significantly more likely to make a specific disclaimer about e-cigarettes' efficacy as a cessation aid (64.9% vs 43.7%).

### DISCUSSION

The number of e-cigarette brands sold on the internet is large and the variety of flavours staggering: more than 460 brands and 7700 flavours. Many of these brands were new in the sense that they were not found in our first comprehensive internet

search in 2012.<sup>24</sup> During the 17 months between the two searches (from August 2012 to January 2014), the number of brands increased by 10.5 per month and 242 new flavours were added to the menu of choices.

The present study focused on internet websites because analysis of the changing content of these websites could offer insights into the dynamics of the unregulated e-cigarette market. E-cigarettes were originally invented to mimic conventional cigarette smoking as closely as possible.<sup>27–29</sup> They are still mostly called e-cigarettes by users because of a certain similarity to cigarettes. Over time, however, the product design has evolved and the advertising messages have changed.

In terms of product design, this study found that older brands were more likely than newer brands to anchor themselves to conventional cigarettes. They were more likely to offer cigalike products, whose design might provide users with a sense of continued cigarette smoking.<sup>27–30–31</sup> In contrast, newer websites were more likely to offer eGos and mods, which allow users to manipulate nicotine content or add other ingredients, a degree of customisation not associated with conventional cigarettes.

This shift towards eGos and mods was associated with an explosion of flavours. Websites often sold nicotine liquid (often called e-juice) separately from hardware, making it easy to add a variety of flavourings to the e-juice. Many brands sold similar hardware, perhaps from the same manufacturer, but created their own e-juices and then branded the whole package as if it were entirely new. In this fashion, new brands could come into the market with small hardware modifications, but a focus on creative labelling for new flavours.

**Table 4** The likelihood of listing e-liquid ingredients and the five most commonly listed ingredients, 2014

	Older brands* (N=251)		Top-5 vs others p value	Older brands combined (N=251) %	Newer brandst (N=215) Newer brands (N=215) %	Older vs newer brands p value
	Top-5 brands (N=5) %	Other brands (N=246) %				
% listing ingredients	100.0	78.0	<0.01	78.5	71.2	0.07
Mean number of ingredients listed	5.2	4.62	0.52	4.6	4.0	<0.05
Type of ingredients						
Nicotine	100.0	93.2	<0.01	93.4	81.7	<0.05
Propylene glycol	80.0	84.9	0.82	84.8	92.8	0.06
Vegetable glycerine/glycerol	80.0	59.4	0.36	59.9	88.2	<0.01
Flavouring	100.0	70.3	<0.01	71.1	65.4	0.45
Water	20.0	47.9	0.24	47.2	33.3	<0.01

\*Active on the internet in 2012 and 2014.

†Active on the internet in 2014 but not 2012.



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Table 5 Claims made about e-cigarettes, 2014

	Older brands* (N=251)				Newer brands† (N=215)	Older vs newer brands p value
	Top-5 brands (N=5) %	Other brands (N=246) %	Top-5 vs others p value	Older brands combined (N=251) %	Newer Brands (N=215) %	
Healthier than cigarettes	100.0	79.7	<0.01	80.1	59.1	<0.01
Could be used where smoking is banned	100.0	76.0	<0.01	76.5	46.5	<0.01
Cheaper than cigarettes	100.0	69.5	<0.01	70.1	47.0	<0.01
Effective quitting aid (indirect claim)	60.0	60.6	0.98	60.6	48.4	<0.05
Effective quitting aid (direct claim)	0.0	10.2	<0.01	10.0	11.6	0.57
Disclaimer	80.0	64.6	0.49	64.9	43.7	<0.01

\*Active on the internet in 2012 and 2014.

†Active on the internet in 2014 but not 2012.

This change in hardware and flavours suggests that newer brands shifted their emphasis towards consumer choice rather than focusing on advantages over conventional cigarettes. Instead of comparing themselves with cigarettes, newer brands appeared to style themselves as new nicotine delivery systems. The number of flavours available through these e-cigarette brands is so large that it is hard to compare with conventional cigarettes currently sold in the US market, which are allowed only two flavours, tobacco and menthol.<sup>32 33</sup>

Along with the changing product design, the messages these brands used to promote themselves on the internet have also changed. Newer brands were significantly less likely to make those claims that made e-cigarettes controversial in the first place.<sup>28 34 35</sup> They were less likely to claim that e-cigarettes were less harmful than conventional cigarettes. They were less likely to address the question of e-cigarettes' efficacy as a smoking cessation aid. While direct claims about cessation efficacy may be prohibited by law, it is easy to make indirect claims about cessation through testimonials. However, newer brands were significantly less likely to do so. They were also less likely to mention that e-cigarettes could be useful substitutes in places where cigarette smoking is not allowed. Finally, they were less likely to compare their price with that of conventional cigarettes. In short, newer brands seem to be moving away from using cigarettes as the reference.

This contrast in product design and advertising message is most salient when comparing the top-5 older brands with newer brands. These five brands clearly anchored themselves to conventional cigarettes. They all offered cigalike products (compared with only 52% of newer brands) and limited their flavours, with NJOY offering only tobacco and menthol. The top-5 brands were much more likely to claim the relative advantage of using e-cigarettes. All claimed their e-cigarettes were less harmful than cigarettes. All of them mentioned that they could be consumed in places where smoking is not allowed, and 80% mentioned that they were cheaper than cigarettes.

What are the regulatory implications of this analysis? To begin with, the following discussion assumes that e-cigarettes will continue to be legally available in one form or another. It also assumes that cigarettes, the most deadly tobacco product available, will continue to be legal for the foreseeable future.

Given that cigarettes are available, an important frame of reference in regulating e-cigarettes is how the use of e-cigarettes impacts the smoking prevalence of a given population. Even though the risk of long-term e-cigarette use is unknown, most tobacco control researchers would agree that these risks are likely much smaller than those associated with continued

cigarette smoking at the individual level. However, people disagree sharply when it comes to the impact of e-cigarette use on smoking prevalence at the population level. There are arguments on both sides<sup>27 30 36</sup>; one side is concerned that the increasing use of e-cigarettes will promote cigarette smoking. The other argues that e-cigarettes will help current smokers quit smoking, increasing the population cessation rate.

Given that there is no hard evidence for the impact of e-cigarettes on smoking prevalence in either direction at this point, it seems prudent that regulations on e-cigarettes be carried out in two phases.

The first phase of regulation would focus on minimising the risks associated with the e-cigarette products themselves. E-cigarette companies should be required to properly list ingredients and nicotine strengths, and follow good manufacturing practices to ensure the safety of their products and avoid adulteration and misbranding.<sup>37</sup> Containers for e-liquid should be required to be child-proof, ensuring that children are unable to swallow large doses of nicotine-containing liquids. No claim regarding efficacy for quitting or any other outcome should be allowed without evidence. Sale to minors should be banned. The clean indoor air policy restricting cigarette smoking should be applied to e-cigarettes as well. These basic policies will help protect consumers from substandard products and reduce the chance of children being put at risk.<sup>38 39 40</sup> Most of these have been included in European regulations on e-cigarettes and the recently issued deeming proposal by the US FDA.<sup>19 41</sup> The present study found that many brands have chosen to list their ingredients, but it is not clear how accurate the lists are. The rules the FDA has just proposed, once put into effect, will help reduce product impurities and standardise information on nicotine content so that e-cigarette users can be more informed about the products they are using.

Restrictions on the use of e-cigarettes indoors does not fall under the purview of FDA regulation, but local or state level ordinances have already been passed in many places. One rationale for these policies is to help protect the anti-smoking social norms.<sup>36</sup> As shown in table 5, many e-cigarette websites advertise their products as a way of getting around existing secondhand smoke policies, a message that could have a detrimental effect on the current tobacco control norm.

The second phase of regulation requires more data. Several important research questions arose from the present study. The study shows that as the product design shifted from cigalikes towards eGos/mods, the advertising messages associated with these products also changed. Does this shift in advertising messages anticipate changing user characteristics? Will there be a



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differential effect of these two types of products either on smoking cessation or on smoking uptake?

More specifically, which product, cigalike or eGo/mod, will be more likely used by smokers to switch completely from conventional cigarettes to e-cigarettes? And which is more likely to be associated with prolonged dual use? Furthermore, which product appeals more to non-smoking youth and which is associated with a greater transitional probability to conventional cigarettes? Is it possible that the newer products, which continue to move away from being cigarette-like, will actually render conventional cigarettes unattractive to youth? Or will the great availability of flavours in the new products lead to a dramatic increase of e-cigarette users such that even a small probability of transition from these users will lead to a large number of new smokers? These are critical questions that future research needs to address to help formulate policies in the next phase of regulation.

A two-phase regulation approach might seem slow, but it is prudent given our current lack of knowledge. For example, regulation could severely restrict flavours based on the assumption that flavoured products will appeal to youth<sup>42, 43</sup> and that the use of e-cigarettes will lead more youth to smoke cigarettes. However, such regulation may primarily benefit the established brands, such as the top-5 in this study, which offer mainly cigalike products (in design and in flavour), rather than actually reducing smoking prevalence. It is conceivable that youth may turn to cigalike products if the more flavoured eGo types are not available. If the transition probability to smoking from these cigalike products is actually higher, then the restriction in flavouring will actually lead to more smokers in the long run. In other words, the existing vibrant e-cigarette market described in this study suggests that regulation based on insufficient scientific data might run the risk of only changing the market share of different e-cigarette brands rather than smoking prevalence itself. The implementation of the currently proposed FDA rules may or may not significantly reduce the number of brands that are owned by small companies. But stricter requirements, such as those similar to the FDA drug approval process, would certainly favour brands with strong financial backing. Most of those brands would be owned by tobacco companies. Obviously, tobacco companies will be more concerned with protecting their cigarette market share than companies that do not produce cigarettes. Regulatory policy making should be concerned with unintended consequences. A key objective of e-cigarette regulation should still be to strive for a net positive effect on smoking prevalence.

### What this paper adds

- This paper presents the first comprehensive study of e-cigarette brands sold on the internet and found that the number of e-cigarette brands and the variety of flavours they offer are very large (more than 460 brands and 7700 flavours).
- Older brands of e-cigarettes were more likely to highlight their advantages over conventional cigarettes, whereas newer brands were more likely to emphasise consumer choice in models and in flavours.
- The dynamics of the current e-cigarette market present significant challenges to regulatory policy making.

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## REFERENCES

- 1 Farsalinos KE, Romagna G, Tsiapras D, *et al.* Characteristics, perceived side effects and benefits of electronic cigarette use: a worldwide survey of more than 19,000 consumers. *Int J Environ Res Public Health* 2014;11:4356–73.
- 2 Choi K, Forster JL. Beliefs and experimentation with electronic cigarettes: a prospective analysis among young adults. *Am J Prev Med* 2014;46:175–8.
- 3 Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011;106:2017–28.
- 4 Kralikova E, Novak J, West O, *et al.* Do e-cigarettes have the potential to compete with conventional cigarettes?: a survey of conventional cigarette smokers' experiences with e-cigarettes. *Chest J* 2013;144:1609–14.
- 5 Pepper JK, Reiter PL, McRee A, *et al.* Adolescent males' awareness of and willingness to try electronic cigarettes. *J Adolesc Health* 2013;52:144–50.
- 6 Regan AK, Promoff G, Dube SR, *et al.* Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA. *Tob Control* 2013;22:19–23.
- 7 Zhu S, Gamst A, Lee M, *et al.* The use and perception of electronic cigarettes and snus among the U.S. population. *PLoS ONE* 2013;8:e79332.
- 8 Centers for Disease Control and Prevention (CDC). Notes from the field: Electronic cigarette use among middle and high school students—United States, 2011–2012. *MMWR Morb Mortal Wkly Rep* 2013;62:729–30.
- 9 Pearson JL, Richardson A, Niaura RS, *et al.* E-cigarette awareness, use, and harm perceptions in US adults. *Am J Public Health* 2012;102:1758–66.
- 10 Stock K. E-cig startups band together as big tobacco looms—Businessweek. *BusinessWeek: Companies & Industries* February 2013. <http://www.businessweek.com/articles/2014-02-13/e-cig-startups-band-together-as-big-tobacco-looms> (accessed 4 Mar 2014).
- 11 Elliott S. Campaigns for electronic cigarettes borrow from their tobacco counterparts. *New York Times* 6 December 2012. <http://www.nytimes.com/2012/12/06/business/media/campaigns-for-electronic-cigarettes-borrow-from-their-tobacco-counterparts.html> (accessed 11 Mar 2014).
- 12 Richardson A, Ganz O, Stalgaitis C, *et al.* Noncombustible tobacco product advertising: how companies are selling the new face of tobacco. *Nicotine Tob Res* 2014;16:606–14.
- 13 Fitch Ratings. Altria Green Smoke buy highlights industry e-cig interest. *Fitch Ratings* 5 February 2014. [https://www.fitchratings.com/creditedesk/press\\_releases/detail.cfm?pr\\_id=819650](https://www.fitchratings.com/creditedesk/press_releases/detail.cfm?pr_id=819650) (accessed 11 March 2014).
- 14 Craver R. Reynolds to market Vuse at SXSW. *Winston-Salem Journal* 3 March 2014. [http://www.journalnow.com/business/business\\_news/reynolds-to-market-vuse-at-sxsw/article\\_49aee7e8-a313-11e3-b7d0-0017a43b2370.html](http://www.journalnow.com/business/business_news/reynolds-to-market-vuse-at-sxsw/article_49aee7e8-a313-11e3-b7d0-0017a43b2370.html) (accessed 11 Mar 2014).
- 15 Sebastian M. NJOY E-cig TV spot insists 'friends don't let friends smoke'. *Advert Age* 2 January 2014. <http://adage.com/article/media/njoy-e-cig-tv-spot-insists-friends-smoke/290886/> (accessed 11 Mar 2014).
- 16 Wallace B. Smoke without fire. *New York Magazine* 28 April 2013. <http://nymag.com/news/features/e-cigarettes-2013-5> (accessed 11 Mar 2014).
- 17 Stevenson A. NJOY, E-cigarette maker, receives funding valuing it at \$1 billion. *New York Times* 28 February 2014. <http://dealbook.nytimes.com/2014/02/28/njoy-e-cigarette-maker-receives-funding-valuing-it-at-1-billion/> (accessed 11 Mar 2014).
- 18 Wikipedia. Electronic cigarette. Wikipedia, 2014. [http://en.wikipedia.org/wiki/Electronic\\_cigarette](http://en.wikipedia.org/wiki/Electronic_cigarette) (accessed 11 Mar 2014).
- 19 Food and Drug Administration. Deeming tobacco products to be subject to the federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. *Fed Regist* 2014. <http://federalregister.gov/a/2014-09491>.



Original article

- 20 Herzog B, Gerber J. E-cigs revolutionizing the tobacco industry. Wells Fargo Securities 2013. <http://www.smallcapfinancialwire.com/wp-content/uploads/2013/11/E-Cigs-Revolutionizing-the-Tobacco-Industry-Interactive-Model.pdf> (accessed 11 Mar 2014).
- 21 Euromonitor International. E-cigarettes: A US\$2 billion global industry—who should be worried? *Euromonitor International* 23 November 2012. <http://blog.euromonitor.com/2012/11/e-cigarettes-a-us2-billion-global-industry-who-should-be-worried.html> (accessed 11 Mar 2014).
- 22 Noel JK, Rees VW, Connolly GN. Electronic cigarettes: A new 'tobacco' industry? *Tob Control* 2011;20:81–81.
- 23 The Smoke Free Alternatives Trade Association. FDA corrects misleading Wall Street Journal report regarding the ban on electronic cigarette online sales. *Smokefree Alternatives Trade Association* 27 August 2013. <http://www.sfata.org/fda-corrects-misleading-wall-street-journal-report-regarding-the-ban-on-electronic-cigarettes-online-sales/> (accessed 11 Mar 2014).
- 24 Lee M, Zhu S, Huang Y, et al. A survey of more than 250 E-cigarette brands on the internet. Poster P053-73. Presented at the Society for Research on Nicotine and Tobacco (SRNT) 19th Annual Meeting; Boston, MA, 13–16 March 2013.
- 25 Richardson A, Ganz O, Vallone D. Tobacco on the web: Surveillance and characterisation of online tobacco and e-cigarette advertising. *Tob Control*. Published Online First: 14 February 2014. doi:10.1136/tobaccocontrol-2013-051246
- 26 The R Project for Statistical Computing. An introduction to R. The R Project for Statistical Computing, 6 March 2014. <http://cran.r-project.org/doc/manuals/R-intro.html> (accessed 11 Mar 2014).
- 27 Cahn Z, Siegel M. Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes? *J Public Health Policy* 2011;32:16–31.
- 28 Bell K, Keane H. Nicotine control: E-cigarettes, smoking and addiction. *Int J Drug Policy* 2012;23:242–7.
- 29 Etter J, Bullen C. Electronic cigarette: Users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011;106:2017–28.
- 30 Polosa R, Rodu B, Caponnetto P, et al. A fresh look at tobacco harm reduction: the case for the electronic cigarette. *Harm Reduct J* 2013;10:19.
- 31 Caponnetto P, Campagna D, Papale G, et al. The emerging phenomenon of electronic cigarettes. *Expert Rev Respir Med* 2012;6:63–74.
- 32 United States Congress. Family smoking prevention and tobacco control act. 2009; H.R. 1256(111);H.R. 1256.
- 33 Mitka M. FDA exercises new authority to regulate tobacco products, but some limits remain. *JAMA* 2009;302:2078–81.
- 34 Paek H, Kim S, Hove T, et al. Reduced harm or another gateway to smoking? source, message, and information characteristics of e-cigarette videos on YouTube. *J Health Commun* 2014;19(5):545–60.
- 35 Benowitz NL, Goniewicz ML. The regulatory challenge of electronic cigarettes. *JAMA* 2013;310:685–6.
- 36 Fairchild AL, Bayer R, Colgrove J. The Renormalization of Smoking? E-Cigarettes and the Tobacco "Endgame". *N Engl J Med* 2014;370:293–5.
- 37 US Food and Drug Administration. Regulation of E-cigarettes and other tobacco products. US Food and Drug Administration, 2011. <http://www.fda.gov/newsevents/publichealthfocus/ucm252360.htm> (accessed 11 Mar 2014).
- 38 CBS News Staff. Electronic cigarette explodes in man's mouth, causes serious injuries. *CBS NEWS* 16 February 2012. <http://www.cbsnews.com/news/electronic-cigarette-explodes-in-mans-mouth-causes-serious-injuries/> (accessed 11 Mar 2014).
- 39 Williams M, Villarreal A, Bozhilov K, et al. Metal and silicate particles including nanoparticles are present in electronic cigarette cartomizer fluid and aerosol. *PLoS ONE* 2013;8:e57987.
- 40 Durmowicz EL. The impact of electronic cigarettes on the paediatric population. *Tob Control* 2014;23(Suppl 2):ii41–6.
- 41 European Parliament, Council of the European Union. Directive 2014/40/EU of the European Parliament and of the Council. *Official Journal of the European Union*, L 127, 29 April 2014. [http://ec.europa.eu/health/tobacco/docs/dir\\_201440\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf) (accessed 6 May 2014).
- 42 Carpenter CM, Wayne GF, Pauly JL, et al. New cigarette brands with flavors that appeal to youth: Tobacco marketing strategies. *Health Aff (Millwood)* 2005;24:1601–10.
- 43 Choi K, Fabian L, Mottey N, et al. Young adults' favorable perceptions of snus, dissolvable tobacco products, and electronic cigarettes: Findings from a focus group study. *Am J Public Health* 2012;102:2088–93.

## Bilag 3 – Government response to the consultation on statutory fees for producers of e-cigarette products



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# Government response to the consultation on statutory fees for producers of e-cigarette products

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1. The Medicines and Healthcare products Regulatory Agency (MHRA) received 102 responses to its consultation on new fees to cover regulatory activity relating to E-cigarette products under the provisions of the revised EU Tobacco Products Directive (2014/40/EU). Of these, 90 were substantive responses offering opinion or information; the remainder were requests for clarification.
2. The largest group of respondents were small e-cigarette/vaping businesses and the trade associations that represent them; however responses were also received from e-cigarette users, the public, the Royal College of Nursing and Action on Smoking and Health (ASH). Two responses were also received from larger tobacco companies.
3. Of the 90 substantive responses:
  - a) 68 respondents (76%) were against the proposals
  - b) 4 respondents (4%) agreed with the proposals
  - c) 14 respondents (16%) agreed in principle with the charging of fees but expressed concerns about the impact
  - d) 4 respondents (4%) provided data or information but did not express an opinion and are judged to be of neutral opinion.
4. New information was provided at consultation that previous volume estimates had been too low. Based on calculations and estimates provided by industry and trade associations, it is now estimated that MHRA may expect as many as 14,000 notifications in the first year (20 May 16 to 31 Mar 17). This is the median number of notifications based upon a set of the most credible data and estimates, accounting for possible attrition in the first year (products currently on the market that will be taken off the market in Year 1). However there remains uncertainty in both this revised volume estimate and the way in which the market will behave following the implementation of the Directive.
5. The consultation asked whether respondents would prefer a fixed fee for a set number of substantial modifications to be added to the periodic fee instead of being charged per substantial modification. Most respondents did not express an opinion and of the small number that did, the feeling was mixed. No new evidence was provided to demonstrate that this would be proportionate and the assumption remains therefore that this would penalise smaller businesses for the larger numbers of substantial modifications made by others. The fee for notifying a substantial modification and the periodic fee will remain therefore separate

and businesses will be charged according to the number of substantial modifications they wish to make. Suggestions of a sliding scale of fees based on turnover, or discounts for multiple applications were also discounted for this reason: they would result in some businesses paying higher costs to subsidise others paying lower costs.

6. Based on the new higher volume estimates provided by industry the fees as proposed at consultation are judged to be high and could run the risk of over recovery against costs. Using the new volume estimate, along with an appreciation of the remaining significant uncertainty, it has been possible to reduce the fees as follows:

Fee Description	Proposed fee (revised following consultation) £
Initial Notification fee	150
Notification (Modification) fee	80
Annual (Periodic) fee	60

7. Pre-consultation, the proposed fees had been set at £220, £110 and £60 respectively.
8. It is Government policy to recharge costs of regulating e-cigarettes back to the e-cigarette industry and MHRA may not cross-subsidise this work from the taxpayer or other business sectors. However the fees will be reviewed annually to ensure that MHRA's costs relating to the regulation of e-cigarettes continue to be recovered in a fair and proportionate way. Due to the remaining significant uncertainty both in the volumes and the fixed technology costs required to connect to the EU Portal for notifying e-cigarette products, the volume of notifications received in Year 1 and the costs will be reviewed, with upward or downward adjustments to fees being made as necessary in following years to ensure neither under- or over-recovery of costs. This will be done through working with the industry as well as through the use of real data on volumes of notifications being submitted to MHRA.
9. A number of respondents were concerned that as retailers or direct resellers the notification fees would apply to them. They do not, but if a retailer rebrands another company's product, imports directly from a foreign manufacturer or assembles e-cigarette products themselves, they become a producer and must notify their products under the Directive, thereby becoming liable to pay the appropriate fees.
10. Several smaller businesses expressed concern that the fees were disproportionate and when calculated across their product range could reduce the viability of their business. While MHRA

must recover its costs, the new reduced fees will now have a lower impact upon small businesses which are trading legitimately in products that meet EU safety standards, and also upon the consumers to whom some or all of this cost may have been passed on. It is also likely to have a lower impact upon the variety of products available to ex-smokers or those wishing to quit. MHRA will continue to work with the sector with the aim of ensuring a fair and proportionate fee regime, both in its structure and cost, that best reflects the sector as it develops.

11. Those expressing an opinion on whether the fees represent 'gold plating' of the EU Tobacco Products Directive (two respondents) agree that MHRA has not gold plated the Directive. Others who agreed in principle mostly felt that MHRA had kept the fees as low as possible, but that the volumes had been underestimated. This has now been rectified with the new lower fee based on a higher estimate of notification volumes.
12. MHRA thanks all respondents for their contributions and intends to proceed with legislation to implement the new fees.
13. Annex A contains a list of companies and organisations that responded to the consultation. Annex B comprises a revised Impact Assessment for the new fees.

**Medicines and Healthcare products Regulatory Agency**

**April 2016**



## ANNEX A

### LIST OF RESPONDENTS: COMPANIES AND ORGANISATIONS<sup>1</sup>

Action on Smoking and Health (ASH)  
Adcentiv Media Retail Ltd t/a VapourOhm  
Alauna Vapour Store  
British American Tobacco UK  
Broughton Laboratories  
Cartridgecom Ltd t/a Vape Monster  
CGChemX Ltd  
Channel 2015  
Chemular Regulatory Consultants  
CloudStix  
Concept Liquids  
Cuts Ice  
Decadent Vapours Ltd  
ECITA (EU) Ltd  
EECBA  
Eos Leisure Ltd t/a Vapemate  
eShisha Club  
Evapo  
Fontem Ventures  
FRESH Imports 2015  
Freshmist E-liquid Manufacturer Ltd  
Generals Juices Ltd  
Go Vapour UK Ltd  
Green Vape Ltd  
Ice Vapour  
Independent British Vape Trade Association (IBVTA)  
JCVAPE  
JTI UK  
Kick Ash Luxury Vapes  
Lee Vapours Ltd  
Liberty Flights Ltd  
Lime-IT Ltd t/a Crème de Vape  
Lonjas UK  
Lumoliquids  
Madvapes UK Ltd  
Nicogreen Ltd

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<sup>1</sup> Individual citizens who responded directly, including those who told us they ran an e-cigarette business but did not indicate its name, are not included in this list. Their responses were still included in the analysis.

Nictel (UK) Ltd  
Queen Mary University of London  
RITCHY EU s.r.o.  
Smokijoes  
SMOKO  
The Ace of Vapez  
The Royal College of Nursing  
The Vapour Loft Ltd  
TJDM Services  
Tor Vapour  
Totally Wicked Ltd  
Valley Vapes  
Vape Club  
Vape Compliance Ltd  
Vape Importers Ltd  
Vape Nation  
Vapeiteasy.net  
VaperCrew eLiquids Ltd  
Vapers In Power  
Vapes Direct Ltd  
Vapourium Ltd  
V-juice Corporation  
WhiteMist Eliquid Ltd  
Wild Juice Chase  
Xyfil Ltd  
ZD Vapes

## Bilag 4 – The Electronic Cigarettes etc. (Fees) Regulation 2016

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### STATUTORY INSTRUMENTS

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2016 No. 521

### CONSUMER PROTECTION

### FEES AND CHARGES

#### The Electronic Cigarettes etc. (Fees) Regulations 2016

<i>Made</i>	- - - -	<i>20th April 2016</i>
<i>Laid before Parliament</i>		<i>25th April 2016</i>
<i>Coming into force</i>	- -	<i>20th May 2016</i>

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a) and section 56(1) of the Finance Act 1973(b).

The Secretary of State has been designated for the purpose of section 2(2) of the European Communities Act 1972 in relation to nicotine and nicotine products(c).

The Treasury has consented to the making of these Regulations as required by section 56 of the Finance Act 1973.

#### Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Electronic Cigarettes etc. (Fees) Regulations 2016 and shall come into force on 20th May 2016.

(2) In these Regulations, “the 2016 Regulations” means the Tobacco and Related Products Regulations 2016(d).

#### Notification fee

2.—(1) A fee is payable in respect of each notification submitted to the Secretary of State under regulation 31(1) of the 2016 Regulations (notification about electronic cigarettes and refill containers).

(2) The amount of the fee payable is £150 except where the notification under regulation 31(1) of the 2016 Regulations is submitted pursuant to regulation 31(2) of the 2016 Regulations (substantially modified products) in which case the amount is £80.

(3) The fee is payable at the time the notification is submitted.

- 
- (a) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).  
(b) 1973 c.51. Section 56(1) was amended by article 6(1)(e) of the Treaty of Lisbon (Changes of Terminology) Order 2011 (S.I. 2011/1043).  
(c) S.I. 2014/2705.  
(d) S.I. 2016/507.

(4) The fee is payable by the person submitting the notification and is payable to the Secretary of State.

#### Annual Fee

3.—(1) An annual fee is payable in respect of each product notified under regulation 31(1) of the 2016 Regulations.

(2) The amount of the annual fee payable is £60.

(3) The annual fee is payable each year on 1st April.

(4) The annual fee is first payable on the first occurring 1st April after the day the product is notified to the Secretary of State.

(5) The fee is payable by the person who submitted the notification and is payable to the Secretary of State.

(6) The annual fee ceases to be payable if the Secretary of State is notified under regulation 31(7) of the 2016 Regulations that the product has been withdrawn from the market; but any annual fee payable prior to the day the Secretary of State is notified remains payable.

#### Adjustment of Fee

4. If, after a notification fee under regulation 2 has been paid, it becomes apparent that—

(a) a lesser fee should have been paid, the excess shall be refunded to the person who paid the fee; or

(b) a higher fee should have been paid, the balance shall become payable by the person who paid the fee within fourteen days commencing with the day that the Secretary of State issues written notice to that person of the correct fee payable.

#### Civil proceedings to recover unpaid fees

5. All unpaid sums due by way of any fees payable under these Regulations shall be recoverable as debts due to the Crown.

Signed by authority of the Secretary of State for Health.

20th April 2016

*George Freeman*  
Parliamentary Under-Secretary of State,  
Department of Health

20th April 2016

*Mel Stride*  
*George Hollingbery*  
Two of the Lords Commissioners of Her Majesty's Treasury

#### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations impose fees on producers of electronic cigarettes and refill containers.

The Tobacco Products Directive 2014(a) (see Title III) places a requirement on the producers of electronic cigarettes and refill containers to notify the national competent authority (NCA) before placing such products on their market. The Directive also imposes a requirement on the Member States to make the notified information publicly available on a website, and empowers Member States to carry out certain supervisory functions with regard to electronic cigarettes and refill containers. In the United Kingdom, these NCA and Member State functions are to be carried out by the Secretary of State for Health (acting by the Medicines and Healthcare Products Regulatory Agency (the MHRA)). This is set out in Part 6 of the Tobacco and Related Products Regulations 2016 which transposes the Tobacco Products Directive in relation to electronic cigarettes and refill containers.

These Regulations supplement the Tobacco and Related Products Regulations 2016 by introducing fees to recover the MHRA's costs. Regulation 2 creates a notification fee to cover the costs of administering the notification scheme. Regulation 3 creates an annual fee to cover the on-going costs of maintaining a website on which notification information is published and carrying out any supervisory activities. Regulation 4 allows for adjustments where the wrong fee is paid under regulation 2. Regulation 5 makes provision to enable recovery of any unpaid fees.

A full impact assessment of the effects that this instrument will have on the costs of business and the voluntary sector is available from the MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ and is published with the explanatory memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).

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(a) Directive 2014/40/EU of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products. OJ L 127, 29.4.2014, p.1 as amended by Commission Delegated Directive 2014/109/EU, OJ L 360, 17.12.2014.



## Bilag 5 – EU's Tobaksvaredirektiv artikel 20

### AFSNIT III

#### ELEKTRONISKE CIGARETTER OG URTEBÅSEREDE RYGEPRODUKTER

##### Artikel 20

##### Elektroniske cigaretter

1. Medlemsstaterne sikrer, at elektroniske cigaretter og genopfyldningsbeholdere kun markedsføres, hvis de overholder dette direktiv og al anden relevant EU-lovgivning.

Dette direktiv finder ikke anvendelse på elektroniske cigaretter og genopfyldningsbeholdere, der er omfattet af et krav om tilladelse i henhold til direktiv 2001/83/EF eller af kravene i direktiv 93/42/EØF.

2. Fabrikanter og importører af elektroniske cigaretter og genopfyldningsbeholdere indgiver en anmeldelse til de kompetente nationale myndigheder i medlemsstaterne af ethvert sådant produkt, som de agter at markedsføre. Anmeldelsen indgives elektronisk seks måneder før den påtænkte markedsføring. For elektroniske cigaretter og genopfyldningsbeholdere, der allerede markedsføres den 20. maj 2016, indgives anmeldelsen senest seks måneder efter den pågældende dato. Der indgives en ny anmeldelse for hver substantiel ændring af produktet.

Anmeldelsen skal, alt efter om produktet er en elektronisk cigaret eller en genopfyldningsbeholder, indeholde følgende oplysninger:

- a) navn og kontaktoplysninger for fabrikanten, en ansvarlig juridisk eller fysisk person i Unionen og i givet fald importøren, der har importeret produktet til Unionen
- b) en liste over alle de ingredienser, der indgår i, og emissioner, der opstår ved anvendelse af, produktet, opdelt efter handelsnavn og type, herunder mængden heraf
- c) toksikologiske oplysninger om produktets ingredienser og emissioner, herunder ved opvarmning, med særlig henvisning til deres virkninger for forbrugernes sundhed ved inhalering, og under hensyntagen blandt andet til eventuelle afhængighedsskabende virkninger
- d) oplysninger om doser og optagelse af nikotin ved forbrug under normale betingelser eller under betingelser, som med rimelighed kan forudses
- e) en beskrivelse af produktets bestanddele, herunder i givet fald elektroniske cigaretters eller genopfyldningsbeholderes åbnings- og genopfyldningsmekanisme
- f) en beskrivelse af produktionsprocessen, herunder om den indebærer serieproduktion, og en erklæring om, at produktionsprocessen sikrer, at kravene i denne artikel er opfyldt
- g) en erklæring om, at fabrikanten og importøren bærer det fulde ansvar for produktets kvalitet og sikkerhed ved markedsføring og anvendelse under normale betingelser eller under betingelser, som med rimelighed kan forudses.

Hvis medlemsstaterne finder, at de indgivne oplysninger er ufuldstændige, kan de anmode om supplerung af de pågældende oplysninger.

Medlemsstaterne kan opkræve forholdsmæssige gebyrer af fabrikanter og importører for modtagelse, lagring, håndtering og analyse af oplysninger, som de modtager.

3. Medlemsstaterne sikrer, at:
- a) nikotinholdig væske kun markedsføres i særlige genopfyldningsbeholdere med et volumen på højst 10 ml, i elektroniske engangscigaretter eller i patroner til engangsbrug, og at patroner og tanke har et volumen på højst 2 ml
  - b) den nikotinholdige væske har et nikotindhold på højst 20 mg/ml
  - c) den nikotinholdige væske ikke indeholder de tilsætningsstoffer, der er opført i artikel 7, stk. 6
  - d) der kun anvendes ingredienser med høj renhed til fremstilling af den nikotinholdige væske. Spor af andre stoffer end de i denne artikels stk. 2, andet afsnit, litra b), nævnte ingredienser forekommer kun i den nikotinholdige væske, hvis sådanne sporbare mængder er teknisk uundgåelige under fremstillingen

29.4.2014

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Den Europæiske Unions Tidende

L 127/27

- e) der, bortset fra nikotin, i den nikotinholdige væske kun anvendes ingredienser, som ikke udgør en risiko for menneskers sundhed i opvarmet eller uopvarmet form
- f) elektroniske cigaretter leverer nikotindoser i konstante mængder ved anvendelse under normale betingelser
- g) elektroniske cigaretter og genopfyldningsbeholdere er børne- og manipulationssikret, er sikret mod beskadigelse og væskeudsvingning og har en mekanisme, der forhindrer væskeudsvingning ved genopfyldning.

4. Medlemsstaterne sikrer, at:

a) enkeltpakninger af elektroniske cigaretter og genopfyldningsbeholdere indeholder oplysninger vedrørende:

- i) brugsanvisning og lagring af produktet, herunder en notits om, at produktet ikke anbefales til brug for unge og ikkerygere
- ii) kontraindikationer
- iii) advarsler henvendt til specifikke risikogrupper
- iv) mulige skadelige virkninger
- v) afhængighedsskabende egenskaber og toksicitet og
- vi) kontaktoplysninger for fabrikanten eller importøren og en ansvarlig juridisk eller fysisk person i Unionen

b) enkeltpakninger og eventuel ydre emballage af elektroniske cigaretter og genopfyldningsbeholdere:

- i) indeholder en liste over alle de ingredienser, der indgår i produktet i aftagende orden efter vægt, en angivelse af produktets nikotinindhold og levering pr. dosis, batchnummer og en anbefaling om at opbevare produktet utilgængeligt for børn
- ii) ikke indeholder elementer eller træk som omhandlet i artikel 13, med undtagelse af artikel 13, stk. 1, litra a) og c), vedrørende oplysninger om nikotinindhold og aromastoffer, jf. dog nærværende litra, nr. i), og
- iii) er forsynet med en af følgende sundhedsadvarsler:

»Dette produkt indeholder nikotin, som er et yderst afhængighedsskabende stof. Det anbefales ikke til brug for ikkerygere»

eller

»Dette produkt indeholder nikotin, som er et yderst afhængighedsskabende stof«

Medlemsstaterne bestemmer, hvilken af disse sundhedsadvarsler der skal anvendes

c) sundhedsadvarslerne overholder kravene fastsat i artikel 12, stk. 2.

5. Medlemsstaterne sikrer, at:

- a) kommerciel kommunikation, som har til formål at fremme salget af elektroniske cigaretter og genopfyldningsbeholdere eller har dette som en direkte eller indirekte virkning, er forbudt i forbindelse med informationssamfundstjenester, i pressen og i de andre trykte publikationer, med undtagelse af publikationer, der udelukkende henvender sig til fagfolk i branchen for elektroniske cigaretter eller genopfyldningsbeholdere, og publikationer, der trykkes og udgives i tredjelande, såfremt de ikke hovedsagelig er bestemt for EU-markedet
- b) kommerciel kommunikation i radioen, som har til formål at fremme salget af elektroniske cigaretter og genopfyldningsbeholdere eller har dette som en direkte eller indirekte virkning, er forbudt



- c) enhver form for offentligt eller privat bidrag til radioprogrammer, som har til formål at fremme salget af elektroniske cigaretter og genopfyldningsbeholdere eller har dette som en direkte eller indirekte virkning, er forbudt
- d) enhver form for offentligt eller privat bidrag til arrangementer, aktiviteter eller enkeltpersoner, som har til formål at fremme salget af elektroniske cigaretter og genopfyldningsbeholdere eller har dette som en direkte eller indirekte virkning, eller som inddrager eller foregår i flere medlemsstater eller på anden vis har virkninger på tværs af grænserne, er forbudt
- e) audiovisuel kommerciel kommunikation, der er omfattet af Europa-Parlamentets og Rådets direktiv 2010/13/EU <sup>(1)</sup>, er forbudt for elektroniske cigaretter og genopfyldningsbeholdere

6. Artikel 18 i dette direktiv finder anvendelse på fjernsalg på tværs af grænser af elektroniske cigaretter og genopfyldningsbeholdere.

7. Medlemsstaterne pålægger fabrikanter og importører af elektroniske cigaretter og genopfyldningsbeholdere hvert år til de kompetente myndigheder at indsende:

- i) udførlige oplysninger vedrørende salgsvolumen, opdelt efter handelsnavn og produkttype
- ii) oplysninger om forskellige forbrugergruppers præferencer, herunder unges, ikkerygeres og de nuværende primære forbrugergruppers
- iii) oplysninger om salgskanaler og
- iv) resuméer af eventuelle markedsundersøgelser, der er gennemført med hensyn til ovenstående, herunder en engelsk oversættelse heraf.

Medlemsstaterne følger markedsudviklingen vedrørende elektroniske cigaretter og genopfyldningsbeholdere, herunder eventuel dokumentation for, at brug af produkterne fører til nikotinafhængighed og i sidste ende et traditionelt tobaksforbrug blandt unge og ikkerygere.

8. Medlemsstaterne sikrer, at oplysninger modtaget i henhold til stk. 2 gøres offentligt tilgængelige på et websted. Medlemsstaterne tager ved offentliggørelsen af disse oplysninger behørigt hensyn til behovet for beskyttelse af forretningshemmeligheder.

Medlemsstaterne stiller efter anmodning alle oplysninger modtaget i henhold til denne artikel til rådighed for Kommissionen og andre medlemsstater. Medlemsstaterne og Kommissionen sikrer, at forretningshemmeligheder og andre fortrolige oplysninger behandles fortroligt.

9. Medlemsstaterne pålægger fabrikanter, importører og distributører af elektroniske cigaretter og genopfyldningsbeholdere at etablere og opretholde et system til indsamling af oplysninger om alle formodede sundhedsskadelige virkninger af disse produkter.

Hvis en af disse økonomiske operatører finder eller har grund til at tro, at elektroniske cigaretter eller genopfyldningsbeholdere, som de er i besiddelse af, og som er bestemt til markedsføring eller er markedsført, ikke er sikre eller ikke er af god kvalitet eller på anden vis ikke er i overensstemmelse med dette direktiv, træffer den pågældende økonomiske operatør straks de nødvendige korrigerende foranstaltninger for at bringe det pågældende produkt i overensstemmelse med dette direktiv eller om nødvendigt trække det tilbage fra markedet eller kalde det tilbage. I sådanne tilfælde underretter den økonomiske operatør også straks markedsovervågningsmyndighederne i de medlemsstater, hvor produktet er tilgængeligt eller er bestemt til at blive gjort tilgængeligt, herom og giver nærmere oplysninger om især den sundheds- og sikkerhedsmæssige risiko, og om eventuelle korrigerende foranstaltninger, der er truffet, og resultaterne af de pågældende korrigerende foranstaltninger.

Medlemsstaterne kan også anmode de økonomiske operatører om supplerende oplysninger, for eksempel om sikkerheds- og kvalitetsmæssige aspekter eller eventuelle skadelige virkninger af elektroniske cigaretter eller genopfyldningsbeholdere.

10. Kommissionen aflægger rapport til Europa-Parlamentet og Rådet om de potentielle risici for folkesundheden ved anvendelse af genopfyldelige elektroniske cigaretter senest den 20. maj 2016 og derefter, når det er hensigtsmæssigt.

<sup>(1)</sup> Europa-Parlamentets og Rådets direktiv 2010/13/EU af 10. marts 2010 om samordning af visse love og administrative bestemmelser i medlemsstaterne om udbud af audiovisuelle medietjenester (direktiv om audiovisuelle medietjenester) (EUT L 95 af 15.4.2010, s. 1).

11. I de tilfælde, hvor elektroniske cigaretter og genopfyldningsbeholdere opfylder kravene i denne artikel, og en kompetent myndighed konstaterer eller har rimelig grund til at tro, at bestemte elektroniske cigaretter eller genopfyldningsbeholdere eller en type elektroniske cigaretter eller genopfyldningsbeholdere vil kunne udgøre en alvorlig risiko for menneskers sundhed, kan myndigheden træffe passende midlertidige foranstaltninger. Den underretter straks Kommissionen og de kompetente myndigheder i de øvrige medlemsstater om de foranstaltninger, der er truffet, og om eventuelle baggrundsdata. Kommissionen afgør snarest muligt efter at have modtaget disse oplysninger, om de midlertidige foranstaltninger er berettigede. Kommissionen informerer den pågældende medlemsstat om sine konklusioner, så medlemsstaten kan træffe passende opfølgingsforanstaltninger.

Hvis anvendelsen af dette stykkes første afsnit bevirker, at markedsføringen af bestemte elektroniske cigaretter eller genopfyldningsbeholdere eller en type elektroniske cigaretter eller genopfyldningsbeholdere er blevet forbudt af berettigede grunde i mindst tre medlemsstater, tillægges Kommissionen beføjelse til at vedtage delegerede retsakter i overensstemmelse med artikel 27 vedrørende udvidelse af et sådant forbud til alle medlemsstaterne, hvis en sådan udvidelse er berettiget og står i rimeligt forhold til målet.

12. Kommissionen tillægges beføjelse til at vedtage delegerede retsakter i overensstemmelse med artikel 27 vedrørende tilpasning af sundhedsadvarslens affattelse i denne artikels stk. 4, litra b). Når en sundhedsadvarsel tilpasses, sikrer Kommissionen, at den er faktuel.

13. Kommissionen fastsætter ved hjælp af gennemførelsesretsakter et fælles format for anmeldelsen omhandlet i stk. 2 og de tekniske standarder for genopfyldningsmekanismen omhandlet i stk. 3, litra g).

Disse gennemførelsesretsakter vedtages efter undersøgelsesproceduren i artikel 25, stk. 2.



# DADAFO

Dansk e-Damper Forening  
Danish Vapers Association

## Høringssvar fra DADAFO Dansk e-Damper Forening

**Ang. "Udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.:"**



*"Damp redder liv!" – dampen kan være direkte medvirkende til,  
at børn bevarer deres forældre og bedsteforældre i live i mange flere år...*

### Indholdsfortegnelse

- [1. Hvem er DADAFO - Dansk e-Damper Forening](#)
- [2. Høringssvar til "Udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.:"](#)
- [3. Kontakt - Dansk e-Damper Forening \(DADAFO\)](#)



**DADAFO**Dansk e-Damper Forening  
Danish Vapers Association**Sikkerhedsstyrelsen**Nørregade 63  
6700 Esbjerg**Den 06.05.2016**Til: [sik@sik.dk](mailto:sik@sik.dk)  
Journalnummer: 615-10-00001**1. Hvem er DADAFO - Dansk e-Damper Forening**

**DADAFO** - Dansk e-Damper Forening, er en uafhængig, nonprofit forbrugerorganisation, der er styret af medlemmerne/forbrugerne. Bestyrelsen er valgt af medlemmerne, og foreningen drives for medlemmernes kontingent og deres frivillige donationer. Foreningen har ingen økonomisk forbindelse til hverken tobaks-, medicinal- eller e-cigaret/e-damp branchen. Alt arbejde i foreningen udføres frivilligt på pro bono basis.

**DADAFO** udtaler sig på vegne af de danske e-dampere, samt de rygere som i fremtiden forventes at ville ønske at anvende et e-produkt som et langt mindre skadeligt alternativ til rygning af tobak - eller som et led i et rygestop.

**DADAFO** har p.t. ca. 2.100 registrerede medlemmer, der alle er over 18 år - hvilket er et krav for medlemskab af foreningen. Median-alderen for foreningens medlemmer ligger på ca. 40-42 år. Medlemmerne af DADAFO kommer fra alle egne af landet.

**DADAFO** står altid til rådighed for en udviklende og indbyrdes informativ dialog - og man kan altid kontakte os med eventuelle spørgsmål - [www.dadafo.dk](http://www.dadafo.dk)

**DADAFO** har også en offentlig Facebook-side, hvor interesserede kan følge med i damp-relaterede emner: <https://www.facebook.com/DanskeDamperForening/>

**DADAFO** vil gerne henvise interesserede til at læse foreningens høringssvar til lovforslag L144, der også er relevant for denne bekendtgørelse - høringssvaret kan læses på vores hjemmeside: <http://dadafo.dk/horingssvar-fra-dadafo/>

- eller via Høringsportal.dk:

<http://prodstoragehoeringspo.blob.core.windows.net/26a3ad85-fb74-44e6-8d4d-3f32e6634e26/DADAFO.pdf>

**DADAFO** vil gerne på det kraftigste opfordre interesserede/implicerede til at deltage på årets **Global Forum on Nicotine**, der afholdes i Warszawa den 17. - 18. juni - læs mere om konferencen her: <https://gfn.net.co/>  
Konferencen omhandler bl.a. lovgivning, standarder, implementering og den nyeste uafhængige forskning på området, med deltagere fra hele verden. DADAFO deltager på konferencen, og står gerne til rådighed for introduktion til nogle af foredragsholderne på konferencen.

Se en fuld liste over årets prominente og kompetente talere på konferencen her: <https://gfn.net.co/programme-2016/speakers-2016>



## 2. Høringssvar til “Udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.”

**Generelt:** DADAFO vil gøre opmærksom på, at EU-direktivet og loven samt de tilhørende bekendtgørelser gerne skulle sigte efter at være proportionel – og være med til at gøre mere gavn end skade for forbrugerne.. Som loven og de tilhørende bekendtgørelser er fremsat, er der desværre en overhængende fare for, at der er tale om overregulering – som desværre kan have den uønskede virkning, at producenter vælger at undlade at anmelde deres produkter, og at handlen med e-produkter går “endnu dybere under jorden”.

Dette er ikke ønskeligt, set fra forbrugernes perspektiv. Enhver form for overregulering kan også medføre, at producenter, distributører, forhandlere og forbrugere ihærdigt forsøger at finde “huller” i lovgivningen – specielt hvis loven og de tilhørende bekendtgørelser er for upræcist og vævende formuleret.

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**Ad § 2. Anmeldelsen af elektroniske cigaretter** – Skal hardware uden indhold af nikotinholdig væske (produkter der sælges uden indhold af væsker af nogen art) – også anmeldes? Der ønskes en præcisering af hvilke produkter der skal anmeldes. Loven, L144 specificerer, at den kun er gældende for produkter der indeholder nikotin.

**Ad § 3 - Stk. 2. Ved vurderingen af om der foreligger en væsentlig ændring af den elektroniske cigaret eller genopfyldningsbeholderen ...**

Der ønskes en konkretisering af, hvad der specifikt vil blive betragtet som en væsentlig ændring. Vil det blive betragtet som en “væsentlig ændring”, hvis f.eks. en e-væske producent, ændrer sin leverandør af propylenglykol eller glycerin? Hvis skiftet af leverandør medfører en minimal ændring af renhedsgraden – vil dette blive betragtet som en “væsentlig ændring”?

**Ad § 5. - stk. 2 - ... “oplysninger om produkter med samme sammensætning...”**

Hvad er retningslinjerne for, om et produkt er gebyrpligtigt? DADAFO erfarer, at samtlige produkter skal anmeldes – men skal samtlige tænkelige varianter af produkter også pålægges anmeldelsesgebyrer? Kan det tænkes at anmeldelsesgebyret kan dække for flere ensartede produkter, hvor de respektive produkter blot skal anmeldes samlet? Vil det være muligt for flere producenter at anmelde det samme produkt – og dermed dele udgiften til anmeldelsesgebyret?

**Ad § 8. - stk. 1 - Den årlige indberetning, jf. lovens § 12, stk. 1, skal indeholde oplysninger forbrugergrupperes præferencer...**

Som forbrugerforening, vil dette på mange punkter overskride grænsen for privatlivets fred. Som forbruger kan man nægte at svare på forhandleres spørgsmål ved f.eks. markedsundersøgelser – og hvilke spørgsmål skal/må i så fald stilles til forbrugerne? Er dette lovligt jf. Registerloven?

**Ad § 8. - stk. 3 - Oplysninger om forskellige forbrugergrupperes præference jf. stk. 1 skal indeholde oplysninger om unges, ikke-rygeres og de nuværende primære forbrugergrupperes præferencer.**

Som forbruger, forventer man ikke at en forhandler spørger samtlige kunder om de er “ikke-rygere” – eller om de tilhører de nuværende primære forbrugergrupper. Dette vil klart overskride mange forbrugeres tolerancetærskel for hvad en forhandler kan forvente at man vil oplyse.

Præferencer for “unge” – L144 forbyder specifikt salg af produkter til børn og unge under 18 år – derfor vil det være

**DADAFO**Dansk e-Damper Forening  
Danish Vapers Association

svært at indhente forbrugeroplysninger på denne forbrugergruppe – da der slet ikke må sælges produkter til denne aldersgruppe..

Medfører kravet om en årlig indberetning af præferencer indenfor forskellige forbrugergrupper, at forbrugerne skal registreres af forhandleren – med navn, køn, alder, nuværende samt tidligere forbrug af andre nikotinprodukter m.m. – dette synes at være tilfældet, da man ellers ikke vil kunne sikre at oplysningerne er unikke, med mindre kunderne er stamkunder i en forretning. Vi synes dette lyder problematisk i forhold til både privatlivet, samt Registerloven?

Det skal som minimum oplyses af forhandlerne i både fysiske butikker og på online handelssteder, at de indberetter disse oplysninger til Central Entry Gate – og at disse oplysninger skal fremsendes i anonymiseret form. Det skal også understreges, at forbrugerne ikke er forpligtet til at besvare forhandleres spørgsmål.

**Ad § 12. - Gebyrer - Fabrikanter og importører skal indbetale et gebyr på 36.900 kr. pr. produkt for anmeldelse efter § 2, stk. 1, og et gebyr på 14.700 kr. pr. produkt for årlig opretholdelse af anmeldelsen...**

**DADAFO** vil endnu en gang, jf. vores møde med Sikkerhedsstyrelsen m.fl. den 04.02.2016 – gøre opmærksom på, at størrelsen på gebyret ikke står mål med de mange forskellige produkter der forventes at ville søge anmeldelse – hvis blot gebyret for anmeldelse er sat på et tilstrækkeligt lavt niveau så alle kan være med – også de små og mellemstore producenter. Der er langt flere produkter der gerne vil være lovligt på markedet, end de estimerede ca. 466 produkter, som det skønnes via WHO-rapporten <sup>1</sup>, som vi omtalte på mødet 04.02.2016. Endnu engang vil vi også understrege at WHO-rapporten ikke tæller antal af produkter, men antallet af brands/varemærker, og at selve grundlaget for WHO's tal specificerer at antallet af unikke smage var er tæt på 8.000 i januar 2014 <sup>2</sup>, dette skal multipliceres med antallet af nikotin og base varianter – dvs. et antal af varianter som ligger flere størrelsesordner højere end det estimat som Sikkerhedsstyrelsen har haft som grundlag for deres økonomiske analyse.

Gebyret er p.t. sat alt for højt, set i forhold til de præferencer der eksisterer på markedet i dag, og gebyrets størrelse vil sætte en kraftig begrænsning på hvor mange producenter der vil finde det attraktivt at sætte sine produkter til salg i Danmark. Specielt når antallet af kunder og potentielle kunder (rygere der gerne vil skifte røg-tobak ud med damp) er så forholdsvis lille, set i forhold til andre af de større EU-medlemslande, der også har et større kundepotentiale. Indberetningen via Central Entry Gate giver ikke mulighed for en "rabat-ordning", såfremt en producent ønsker at anmelde sine produkter i flere eller samtlige EU-medlemslande på samme tid. Producenterne vil fortrinsvis ønske at anmelde deres produkter i de lande der har den største potentielle kundegruppe – og i de lande hvor introduktionsgebyret/anmeldelsesgebyret er fornuftigt sat rent prismæssigt.

Dermed bliver Danmark at betragte som et damp-U-land, hvor kun få produkter vil blive anmeldt – og dermed stoppes al form for innovation og konkurrence – og forbrugerne får ikke det brede udvalg af produkter at vælge imellem, som de ellers ville kunne have fået, hvis gebyrets størrelse gav mulighed for større konkurrence og større udbud af forskellige producenters produkter. Der er ikke tale om produkter under betegnelsen "one size fits all" – men der er i høj grad tale om et udpræget ønske om variation i produkterne – både designmæssigt og teknisk set. Gebyrets størrelse tilgodeser de store globale producenter (læs: tobaks og medicinal industrien) – hvis produkter er forholdsvis enkle og ikke findes i mange forskellige varianter – produkter som i mange forbrugerens øjne hverken er effektive nok eller af en god nok kvalitet.

<sup>1</sup> [http://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\\_10-en.pdf](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf)

<sup>2</sup> [http://tobaccocontrol.bmj.com/content/23/suppl\\_3/iii3.full](http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3.full)

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Danish Vapers Association

Gebyrerne der pålægges produkterne vil i sidste ende medføre et mindre udvalg, som vil ende med dyrere produkter – som igen vil resultere i at færre rygere finder et skifte fra røg til damp attraktivt. Så snart det økonomiske incitament forsvinder, vil færre rygere overveje at skifte røgtobakken ud med damp.

**DADAFO** vil endnu en gang opfordre til, at produkter som har samme basale ingredienser/primær recept – blot i forskellige blandingsforhold, bør betragtes som værende ét produkt – der anmeldes og godkendes til markedsføring med maksimalt indhold af nikotin på 20 mg/ml. Alle andre varianter af samme e-væske, er at betragte som generiske produkter, som er dækket af den samme anmeldelse. Rent sikkerhedsmæssigt er det p.t. ud fra det nuværende videnskabelige grundlag ikke væsentligt, om en e-væskes blandingsforhold er med større eller mindre andel af propylenglykol og glycerin – og om nikotinindholdet i væsken er max. 20 mg/ml eller blot 3 mg/ml. Indholdet af aromastoffer er for så vidt det samme, hvad enten væsken produceres med forskelligt blandingsforhold af de øvrige ingredienser. Set ud fra et rent sikkerhedsmæssigt aspekt, så er det ikke indholdet af de basale ingredienser (PG, VG, vand og nikotin) som er problematiske, selvom det naturligvis er vigtigt at dette bliver korrekt videregivet som information til forbrugeren. Det er i aromastofferne man evt. kan finde problemstoffer som kan have store fysiologiske og biologiske virkninger ved inhalation. Derfor giver det mere mening at betragte baserne som generiske produkter.

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### 3. Kontakt - Dansk e-Damper Forening (DADAFO)

**DADAFO** - Dansk e-Damper Forening, står til rådighed for konsultation i forbindelse med lovens konkrete indhold og udformning.

Sikkerhedsstyrelsen m.fl. er altid meget velkommen til at kontakte forbrugerorganisationen for yderligere oplysninger.

På foreningens vegne ...

#### **Kim Dabelstein Petersen - Formand**

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#### **Interessekonflikter/Disclaimer:**

- **DADAFO** - Dansk e-Damper Forening, er en uafhængig, nonprofit forbrugerorganisation, der er styret af medlemmerne/forbrugerne. Bestyrelsen er valgt af medlemmerne, og foreningen drives for medlemmernes kontingent og deres frivillige donationer. Der er ingen økonomisk forbindelse til hverken tobaks-, medicinal- eller e-cigaret/e-damp branchen. Alt arbejde i foreningen udføres frivilligt på pro bono basis.
- **DADAFO** taler på vegne af de danske e-dampere, samt de rygere som i fremtiden forventes at ville ønske at anvende et e-produkt som et alternativ til rygning af tobak - eller som et led i et rygestop.
- **DADAFO** har p.t. ca. 2.100 registrerede medlemmer, der alle er over 18 år - hvilket er et krav for medlemskab af foreningen. Median-alderen for foreningens medlemmer ligger på ca. 40-42 år. Medlemmerne af DADAFO kommer fra alle egne af landet.
- **DADAFO** står altid til rådighed for en udviklende og indbyrdes informativ dialog - og man kan altid kontakte os med eventuelle spørgsmål - [www.dadafo.dk](http://www.dadafo.dk)



**From:** Branka Klisura  
**Sent:** 9 May 2016 08:22:03 +0200  
**To:** Mathilde Horsman Jensen  
**Subject:** VS: Høringssvar på Sikkerhedsstyrelsen bekendtgørelse vedr. e-cigaretter.

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**Branka Klisura**

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**Fra:** Henrik Damgaard [<mailto:hd@esug.dk>]  
**Sendt:** 5. maj 2016 13:08  
**Til:** Branka Klisura  
**Emne:** Høringssvar på Sikkerhedsstyrelsen bekendtgørelse vedr. e-cigaretter.

§2.2            Hvis ikke et produkt bliver godkendt af sikkerhedsstyrelsen, hvad så med betalingen ? Får man pengene retur?

§12            Som jeg ser det, er hele hensigten med loven vedr. e-cigaretter er at sikre forbrugeren anvender et sikkert og godkendt produkt. Samtidig kan det konstateres at brugerne af e-cigaretter kontinuerligt efterspørger nyheder, og herunder især forskellige e-væsker. Et for højt gebyr på e-væsker vil få den utilsigtede virkning, at brugerne i stedet vil blande e-væske selv, da ingredienserne hertil IKKE er pålagt nogen afgifter. Så vi vil få en nation af e-cigarett brugere, der vil sidde hjemme i køkkenet og blande/mikse deres egne væsker, hvor forhold som rengøring, hygiejne, temperatur m.v. jo slet ikke kan sammenlignes med de nærmest "medicinske" forhold, som professionelle producenter af e-væsker producerer under. En afgift på kr. 36.900 pr e-væske (styrke og smag) vil efter min mening, og argumenter, være et totalt selvmål for målsætningen med loven, og ligeledes ødelægge markedet for e-væske i Danmark. Og ikke bare ødelægger det markedet, for et så højt afgiftsniveau vil ingen af de nuværende forhandlere kunne betale. Til illustration heraf ser kalkulationen således ud for min virksomhed:

- Antal e-væsker i sortiment ca. 200.
- Antal baser i sortiment 7 stk.
- Styrker i dag: 3mg, 6 mg, 12mg, og 18mg
- Dvs. en indmeldelse af mit nuværende sortiment koster Kr.  $36.900 \times 207 \times 4 =$  Kr. 30.553.200,-
  - o Og en årlig omkostning til opretholdelse af godkendelsen på kr.  $15.900 \times 207 \times 4 =$  Kr. 13.165.200,-
- Dertil kommer indmeldelses gebyr og årlig vedligeholdelse til "hardware produkter"

Dette er blot tal for min virksomhed alene. Dette er jo langt mere end virksomheden omsætter for.....Sikkerhedsstyrelsen opererer med en model hvor afgiftsprovenuet for ALLE forhandlere i DK skal modsvare en omkostning på Kr. 10.800.000,-, så der må jo være nogen der har regnet helt forkert.....Det er kort sagt en ommer!!!

e-cigaret brugerne vil have mangfoldighed i markedet vedr. e-væsker, og derfor vil et for højt afgifts niveau betyde at det danske marked bliver en selvblander marked, eller kunderne vil købe det i f.eks. England, hvor notifikationsgebyret KUN er £150,- Så er jeg godt klar over, at jfv TPD'en, så skal UK baserede virksomheder også betale notifikationsomkostningerne i Danmark, men der vil realiteten jo være, at rigtig mange UK baserede webshops vil sende en kundeordre til Danmark, selv om denne notifikation ikke har fundet sted. Så på sigt vil ecigaretbranchen i UK blomstre, hvor den vil blive afviklet i Danmark, og de ca. 3.000 arbejdspladser vi allerede har skabt, vil gå tabt.

Så jeg kan kun opfordre til at evaluere realismen i den model der er kommet i UK, og så udskyde implementeringen i Danmark, indtil der er lavet en samlet beregning for ecigaretbranchen. Det ville være prisværdigt, om det kunne ske sammen med brancheorganisationen i Danmark, BECIG.

Venlig hilsen

Henrik Damgaard  
Indehaver



04. maj 2016

/MajAli-erst

## Høringssvar vedrørende Bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere mv.

Erhvervsstyrelsens Team Effektiv Regulering (TER) har modtaget udkastet i høring.

TER vurderer, at bekendtgørelsesudkastet medfører administrative konsekvenser under 4 mio. kr. årligt for erhvervslivet. De bliver derfor ikke kvantificeret yderligere.

### Kontaktperson vedr. ovenstående bemærkninger:

Lisa Gundsø  
Fuldmægtig  
Tlf. direkte 3529 1141  
E-post: LisGun@erst.dk

*'Fra oktober 2015 skal al regulering med direkte konsekvenser for erhvervslivet jf. Vejledning om erhvervsøkonomiske konsekvensvurderinger træde i kraft på en af to fælles ikrafttrædelsesdatoer hhv. 1. januar og 1. juli.'*

Med venlig hilsen

**Maja Alicia Petersen**

Stud.jur., Team Jura

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Sikkerhedsstyrelsen  
[sik@sik.dk](mailto:sik@sik.dk); [brkl@sik.dk](mailto:brkl@sik.dk)

2-05-2016  
Dok. 157425/

**Udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.**

Forbrugerrådet Tænk har modtaget ovenstående udkast til bekendtgørelse i høring. Vi har følgende bemærkninger.

Forbrugerrådet Tænk støtter kraftigt, at fabrikanter og importører er forpligtede til at indberette viden om ingredienser og emissioners kemi og toksicitet samt, at oplysningerne skal være offentligt tilgængelige, og registreres i REACH. Vi ser frem til, at indberetninger vil føre til reel kontrol og vurdering af produkternes sundhedsrisiko.

Vi vil gerne benytte lejligheden til at understrege, at produkter til e-rygning med og uden nikotin bør have samme regulering. Vi mener, at alle produkter til e-rygning bør anmeldes og kontrolleres.

Det er særligt vigtigt, at vi beskytter børn og unge, da de kan være særligt sårbare for udsættelse af e-dampe og e-rygning. Derfor opfordrer Forbrugerrådet Tænk til, at produkter henvendt mod børn med vingummismag mv. også omfattes og særligt også markedsføringen af disse kontrolleres. Tobaksvaredirektivet regulerer søde smage og andre aromaer i tobak og derfor mener Forbrugerrådet Tænk, at dette også bør gælde for e-cigaretter.

Med venlig hilsen

Vagn Jelsø  
Vicedirektør

Sine Jensen  
Seniorrådgiver, sundhedspolitik



**From:** Henrik Herskind  
**Sent:** 3 May 2016 00:23:47 +0200  
**To:** Sikkerhedsstyrelsen Hovedpostkasse (SIK)  
**Subject:** Høringssvar vedr. journalnr. 615-10-00001

Formuleringen i par. 5, stk. 2 om "produkter med samme sammensætning..." Synes meget uklar.  
Hvordan skal bestemmelsen egentlig forstås?  
Skal enhver tænkelig nikotinstyrke i væskerne anmeldes separat (med eget e-cigaret-ID)?  
Og skal enhver tænkelig sammensætning af PG, VG, smagsstof, vand anmeldes separat?

Venlig hilsen,  
Henrik Herskind  
Wagnersvej 4  
2450 Kbh. SV

4. maj 2016

Sikkerhedsstyrelsen  
pr. e-mail [sik@sik.dk](mailto:sik@sik.dk)

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[www.cancer.dk](http://www.cancer.dk)

UNDER PROTEKTION AF  
HENDES MAJESTÆT DRONNINGEN

**Journalnr. 615-10-100001**

**Høring over udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.**

Kræftens Bekæmpelse har med interesse læst udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere.

Som nævnt i tidligere høringssvar vedr. Lov om e-cigaretter, opfordrer Kræftens Bekæmpelse til at e-cigaretter både med og uden nikotin reguleres ens. Bekendtgørelsen omfatter kun e-cigaretter med nikotin. Men der er også målt sundhedsskadelige og kræftfremkaldende stoffer i e-væsker og e-røg uden nikotin. Desuden har flere undersøgelser fundet nikotin i e-væsker, der blev solgt som nikotinfri. Derfor bør også de nikotinfri e-cigaretter og e-væsker m.m. være anmeldelsespligtige og omfattet af denne bekendtgørelse.

Kræftens Bekæmpelse opfordrer til, at der i bekendtgørelsen er særligt fokus på at beskytte børn og unge. De er sårbare i forhold til skadelige indholdsstoffer i e-røgen og det bør sikres, at e-cigaretter ikke bliver indgang til børns og unges tobaksrygning. Derfor bør det ikke være tilladt at markedsføre e-cigaretter og e-væsker med f.eks. smag af slik, cola eller frugt. Tobaksvaredirektivets regulering af søde smage og andre kendetegnende aromaer i tobak bør også omfatte e-cigaretter. Som minimum bør bekendtgørelsen sikre, at e-cigaretten klassificeres efter, om den indeholder kendetegnende aromaer, ligesom det er tilfældet for tobak. Producenternes oplysninger om bestemte forbrugergrupperes præferencer bør suppleres med uafhængige undersøgelser af produkternes appel til børn og unge.

Det fremgår af udkastet til bekendtgørelsen, at fabrikanter og importører er forpligtede til at indberette viden om ingredienser og emissioners kemi og toksicitet mm. Kræftens Bekæmpelse finder det positivt, at oplysningerne om kemi og toksicitet skal være offentligt tilgængelige, og registreres i REACH. Vi håber, at disse indberetninger vil blive brugt til reel kontrol og vurdering af produkternes sundhedsrisiko, samt analyser og forskning i virkning og skadelighed.

**Med venlig hilsen**



Mette Lolk Hanak  
Afdelingschef



PHILIP MORRIS ApS

København den 6. maj 2016

Sikkerhedsstyrelsen  
Nørregade 63  
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Vedr. journalnr. 615-10-00001

**Høringssvar vedrørende** udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.

Kære Branka Klisura

Først og fremmest vil vi gerne takke for muligheden for at kommentere på nærværende udkast til bekendtgørelse.

Philip Morris ApS konstaterer, at regeringen med dette udkast til bekendtgørelse implementerer dele af Europa-Parlamentets og Rådets Direktiv 2014/40/EU af 3. april 2014. Vi har bidt mærke i, at man flere steder i bemærkningerne til selve lovforslaget understreger, at man ikke ønsker at overimplementere. Det er fuldt forståeligt, da direktivet i store træk afspejler det mandat, Europaudvalget gav til forhandlingen af dette i 2013. Vi anerkender naturligvis, at der er megen oversættelse forbundet med at implementere Kommissionens "implementing decision" fra den 24. november 2014 og omsætte den til en dansk bekendtgørelse. Vi har derfor næsten ingen kommentarer, idet vi forstår, at man fra Sikkerhedsstyrelsens side ikke ønsker at gå videre, end hvad der er besluttet på EU-niveau og står i Commission Implementing Decision (EU) 2015/2183. Vi vil anbefale, at man dobbelttjekker oversættelserne, da vi visse steder har observeret at ordlyden ændre sig en smule i den danske oversættelser. Vi er naturligvis klar over, at det ikke altid er muligt, at oversætte én-til-én.

Eksempelvis kan man i Bilag 1, under 6. PRODUKTETS UDFORMNING i feltet e-cigaret\_Produktion\_Overholdelse se, at teksten ikke stemmer overens med det, der står i Commission Implementing Decision (EU) 2015/2183. I (EU) 2015/2183 hedder et felt: "E-cigarette\_Production\_Conformity" og beskrivelsen lyder "Declaration that the production process ensures conformity (including but not limited to information on series production)". I den danske version hedder det "Erklæring om at produktionsprocessen sikrer overholdelse af gældende regler (herunder, men ikke begrænset til, oplysninger om serieproduktion)". Man kunne for klarhedens skyld overveje om der findes en bedre oversættelse, eksempelvis ordet "konformitet", idet henvisningen til "gældende regler" *kan* skabe uklarhed i forhold til originalteksten.

Jeg står naturligvis til rådighed, såfremt ovenstående måtte give anledning til spørgsmål eller behøver yderligere uddybning.

Med venlig hilsen

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**TOBAKS  
PRODUCENTERNE**

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**Sikkerhedsstyrelsen**

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København d. 4. maj 2016

**Vedr. Journal nr. 615-10-00001: Høringssvar udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.**

Tobaksproducenterne takker for muligheden for at afgive høringssvar i forbindelse med udkast til bekendtgørelse om anmeldelse af elektroniske cigaretter og genopfyldningsbeholdere m.v.

Tobaksproducenterne repræsenterer British American Tobacco, JTI og Imperial Tobacco, som tilsammen udgør ca. 85 pct. af det danske cigaretmarked.

Tobaksproducenterne kan med tilfredshed konstatere, at bekendtgørelsen er direktivnær, og vi har derfor kun enkelte bemærkning:

**§ 8 Årlig indberetning af oplysninger**

Paragraffen rejser et spørgsmål. Er en fælles europæiske indberetning tilstrækkelig eller skal de samme markedsundersøgelser indberettes i hvert land? Det bedes præciseres.

Med venlig hilsen



Louise Feilberg  
Direktør Tobaksproducenterne