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**WP4 - D7.4** 

## Report on a proposed system for the reporting of adverse events

JAT( JOINT ACTION ON **TOBACCO CONTROL** 

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## Introduction

The EU Tobacco Products Directive (TPD) 2014/40/ EU9 along with Commission Implementing Decisions EU 2016/586 (2016)10 and EU 2015/2183 (2015)11, has established standards for e-cigarette reporting, product safety and packaging. Specifically, the provisions of EU TPD Article 20 enumerate product labelling, packaging, composition and technical requirements including, but not limited to, child-resistant packaging features, refill container volume, nicotine content levels, health warning labels, informational leaflets, and technical parameters to reduce the risk of spilling during refill or leaking during use.

The overall objective of Task 4.2 within this specific Work Package (WP) is to support the EU MS in the development of a system for the reporting of information of suspected adverse events on human health inline with TPD Art.20(9).

This deliverable (D7.4) presents a short reporting template for the reporting of adverse events both by economic operators (Annex 1) as also by competent authorities (Annex 2).





## Annex 1. Short reporting template for the reporting of adverse events for economic operators

Reporting form o	f suspecte	d adverse effects	(AE) for electror	nic cigarette (	e-cig) and refill liquid		
		Patient	individual data				
1. Initials or Record number 2. Year of		of birth	3. Sex	4. Weight (kg	) 5. Height (cm)		
			□ M □ F				
6. Ethnicity/race (optional)		7. Pregnancy	□NO □YES, W	eek			
( ( )		Breastfeeding	□NO □YES				
	Desc	scription of AE					
8. AE start (date)		9. Causes of AE	•				
during e-cig use		☐ inhalation ☐ e-cig	$\square$ inhalation $\square$ e-cig explosion $\square$ poisoning from the refill liquid (by ingestion) $\square$ skin absorption				
after e-cig use, specify after how long:		more intense use of e-cig, describe					
		Other					
10. Symptoms		11. If use of the e-cig was stopped did the AE stop?					
	ning up of blood	□ headache □ NO □ YES □ dizziness □ 12 Tragtment of the AE					
1_			12. Treatment of the AE				
	_ ' '		□ NO □ YES				
☐ mouth ulcers ☐ sweat	•	☐ tremors	Describe				
dry cough ☐ abdominal pain ☐ restlessness		_					
	ood pressure	☐ tachycardia	13. Seriousnes	s of AF	14. Outcome		
asthma vomiti	•	☐ bradycardia	is. seriousnes	S OI AL	17. Outcome		
shortness of breath skin ra		eye irritation	required a vis		discharged after doctor visit		
			admitted to h	ospital	recovered,		
		burn and scalds	disability life threatening		how long(date)		
<ul><li>□ worsening of pre-existing condition</li><li>□ other</li></ul>	ns:		death	ng	unknown		
15. Comments on causal rela	· _						
☐ certain ☐ likely ☐ p	ossibile 🖵 ur	nlikely <b>u</b> nrelated <b>u</b>	unknown <b>note</b>				
16. Describe any other detail	(e.g. duration	n of the AE, complicatio	ns/sequelae and any	relevant laborato	ory results)		
17. Exclusive use of e-cig	Diver Divo	#	18. Use of E-cig c	ontainina			
dual user, how long							
Duration of smoking before e-cig sto			— a only flavours				
If user of other tobacco product, spe			mixed substances				
20. Nicotine concentration (r	( D.						
rechargeable e-cig (refillable thro		ottle)	21. Duration of e-c	cig use	22. Restart e-cig use after AE		
Technigeable e-cig (reilliable inio	ugii irie e-iiquia b		_ less than 1 month	2-3 months	☐ YES ☐ NO		
disposable e-cig					Symptoms returned		
disposable cartridge			_	0 man 0 monnis	☐ YES ☐ NO		
23. Is the electronic cigarett	e used at the	time of the symptoms th	ne same as normally (	used?	□NO		
_			•				
I .					☐ tobacconist ☐ retail seller ☐ other		
			-				
Specify the new brand (e-cig and/or liquid)Sales point if different							
24. Medications, NRT and/or	-		-		s etc. used at the time of the		
appearance of the AE	ES UNO IF Y	ES Specify					
Dosage, route of administration of	ind duration of	Jse:					
25. Current or past relevant r	nedical histor	y (illnesses, allergies, al	cohol use, drugs of al	ouse, etc.)			
	<del></del>						
		Manufacture	er, importer, distribut	or			
26.		Mandiacidie	, imponer, disimbor	<u>~.</u>			
-3.							
27. date	Send this fo	rm to: Competent authority	or market surveillance	authority			
Address		Email	Fc	ax			

## Annex 2. Short reporting template for the reporting of adverse events for competent authorities

						e-cig) and refill liquid			
Patient individual data									
1. Initials or Record number 2. Year		of birth	3. Sex ☐ M ☐ F	4. Weight (kg)	5. Height (cm)				
6. Ethnicity/race (optional)				7. Pregnancy	□NO □YES, we	eek			
				Breastfeeding □NO □YES					
				ption of AE					
8. AE start (date)			9. Causes of AE						
after e-cig use, specify after how long:		☐ inhalation ☐ e-cig explosion ☐ poisoning from the refill liquid (by ingestion) ☐ skin absorption ☐ more intense use of e-cig, describe							
10. Symptoms			Other						
throat irritation	coughing u	n of blood	headache NO YES						
sore throat	☐ bleeding fo	•							
	☐ dry mouth ☐ anaphylaxis		☐ dizziness						
mouth ulcers			☐ tremors						
☐ dry cough ☐ abdominal pain		☐ restlessness	Describe						
☐ laryngospasm ☐ high blood pressure		☐ tachycardia							
☐ asthma	vomiting		☐ bradycardia	13. Seriousnes	s of AE	14. Outcome			
shortness of breath	skin rash		eye irritation	required a vis	it to doctor	discharged after doctor visit			
☐ bronchospasm			nose irritation	admitted to h		recovered.			
achest pain			$\square$ burn and scalds	disability	056	how long			
worsening of pre-exis	ting conditions:			life threateni	ng	date)			
dother				death		unknown			
15. Comments on c		· _	veen e-cig and AE	oknova					
	<u> </u>		,						
16. Describe any of	her detail (e.ç	g. duratior	of the AE, complication	s/sequelae and any	relevant laborato	ry results)			
17. Exclusive use of	e-cia 🗆 Y	s 🗆 NO	If answered <u>NO</u> specify :	18. Use of E-cig c	ontaining				
dual user, how long				nicotine nicot	tine+flavours, specify_				
Duration of smoking before e-cig start				only flavours					
If user of other tobacco	oroduct, specify_			mixed substances					
20. Nicotine conce	ntration (mg/m	nl):		21. Duration of e-c	cia use	22. Restart e-cig use after AE			
rechargeable e-cig (r	efillable through t	he e-liquid b	ottle)		g 000	YES NO			
				less than 1 month 2-3 months		Symptoms returned			
l				— 4-6 months $\Box$ more than 6 months					
disposable cartridge_						☐ YES ☐ NO			
	_		ime of the symptoms the	-		□ NO			
						$\square$ tobacconist $\square$ retail seller $\square$ other			
If answered No it changed: • e-cig • cartridge • refill liquid • self-made e-cig • self-made/mixed liquid • note									
1 2 Decity the new brown	(e-cia and/or l	iauid)		Sales point i	f different				
24. Medications, NI	RT and/or othe	er product		ants, homeopathic,	food supplements	etc. used at the time of the			
24. Medications, NI appearance of the	RT and/or othe	er product	s based on medicinal pl	ants, homeopathic,	food supplements	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm	RT and/or other AE YES Inistration and d	er product NO If <u>yr</u> Iuration of u	s based on medicinal pla <u>S</u> Specify se:	ants, homeopathic,	food supplements	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm	RT and/or other AE YES Inistration and d	er product NO If <u>yr</u> Iuration of u	s based on medicinal plo S Specify	ants, homeopathic,	food supplements	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm	RT and/or other AE YES Inistration and d	er product NO If <u>yr</u> Iuration of u	s based on medicinal pla <u>S</u> Specify se:	ants, homeopathic,	food supplements	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm	RT and/or other AE YES Inistration and d	er product NO If <u>yr</u> Iuration of u	s based on medicinal plasses; se:  (illnesses, allergies, alco	ants, homeopathic,	food supplements	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm	RT and/or other AE YES Inistration and d	er product NO If <u>yr</u> Iuration of u	s based on medicinal plasses; se:  (illnesses, allergies, alco	ants, homeopathic,	food supplements ouse, etc.)	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm 25. Current or past	RT and/or other AE  YES  inistration and descriptions relevant media	er product No If <u>ye</u> I luration of u  Cal history	s based on medicinal places Specify se: (illnesses, allergies, alco	ants, homeopathic, ohol use, drugs of al	food supplements ouse, etc.)	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm  25. Current or past	RT and/or other AE  YES  inistration and description and descr	er product No If YE  Invarion of C  Cal history	s based on medicinal places based on medicinal places specify	ohol use, drugs of all rinformation 27. Contact detail	food supplements ouse, etc.)	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm  25. Current or past the Dosage of the Dosage, route of adm  26. Title    general doctor	RT and/or other AE  YES  inistration and description and descr	er product  NO If YE  Iteration of C  Cal history  cist  Cist  Cror his/her	s based on medicinal places Specify se: (illnesses, allergies, alco Reporte	ohol use, drugs of all r information 27. Contact detail Name + Surname	food supplements ouse, etc.)	etc. used at the time of the			
24. Medications, NI appearance of the Dosage, route of adm  25. Current or past	RT and/or other AE  YES  inistration and description and descr	er product  NO If YE  Iteration of C  Cal history  cist  Cist  Cror his/her	s based on medicinal places based on medicinal places specify	r information  27. Contact detail Name + Surname Address	food supplements ouse, etc.)	etc. used at the time of the			