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## WP4 - D7.4

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



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## Introduction

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The EU Tobacco Products Directive (TPD) 2014/40/ EU9 along with Commission Implementing Decisions EU 2016/586 (2016)<sup>10</sup> and EU 2015/2183 (2015)<sup>11</sup>, 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 of suspected adverse effects (AE) for electronic cigarette (e-cig) and refill liquid				
Patient individual data				
1. Initials or Record number	2. Year of birth	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F	4. Weight (kg)	5. Height (cm)
6. Ethnicity/race (optional)		7. Pregnancy <input type="checkbox"/> NO <input type="checkbox"/> YES, week _____ Breastfeeding <input type="checkbox"/> NO <input type="checkbox"/> YES		
Description of AE				
8. AE start (date) _____ <input type="checkbox"/> during e-cig use <input type="checkbox"/> after e-cig use, specify after how long: _____		9. Causes of AE <input type="checkbox"/> inhalation <input type="checkbox"/> e-cig explosion <input type="checkbox"/> poisoning from the refill liquid (by ingestion) <input type="checkbox"/> skin absorption <input type="checkbox"/> more intense use of e-cig, describe _____ Other _____		
10. Symptoms <input type="checkbox"/> throat irritation <input type="checkbox"/> coughing up of blood <input type="checkbox"/> headache <input type="checkbox"/> sore throat <input type="checkbox"/> bleeding from the nose <input type="checkbox"/> dizziness <input type="checkbox"/> dry mouth <input type="checkbox"/> anaphylaxis <input type="checkbox"/> vertigo <input type="checkbox"/> mouth ulcers <input type="checkbox"/> sweating <input type="checkbox"/> tremors <input type="checkbox"/> dry cough <input type="checkbox"/> abdominal pain <input type="checkbox"/> restlessness <input type="checkbox"/> laryngospasm <input type="checkbox"/> high blood pressure <input type="checkbox"/> tachycardia <input type="checkbox"/> asthma <input type="checkbox"/> vomiting <input type="checkbox"/> bradycardia <input type="checkbox"/> shortness of breath <input type="checkbox"/> skin rash <input type="checkbox"/> eye irritation <input type="checkbox"/> bronchospasm <input type="checkbox"/> nausea <input type="checkbox"/> nose irritation <input type="checkbox"/> chest pain <input type="checkbox"/> diarrhoea <input type="checkbox"/> burn and scalds <input type="checkbox"/> worsening of pre-existing conditions: _____ <input type="checkbox"/> other _____			11. If use of the e-cig was stopped did the AE stop? <input type="checkbox"/> NO <input type="checkbox"/> YES	
			12. Treatment of the AE <input type="checkbox"/> NO <input type="checkbox"/> YES Describe _____ _____	
			13. Seriousness of AE <input type="checkbox"/> required a visit to doctor <input type="checkbox"/> admitted to hospital <input type="checkbox"/> disability <input type="checkbox"/> life threatening <input type="checkbox"/> death	14. Outcome <input type="checkbox"/> discharged after doctor visit <input type="checkbox"/> recovered, how long _____ <input type="checkbox"/> fatal _____ (date) <input type="checkbox"/> unknown
15. Comments on causal relationships between e-cig and AE <input type="checkbox"/> certain <input type="checkbox"/> likely <input type="checkbox"/> possible <input type="checkbox"/> unlikely <input type="checkbox"/> unrelated <input type="checkbox"/> unknown note _____				
16. Describe any other detail (e.g. duration of the AE, complications/sequelae and any relevant laboratory results) _____ _____				
17. Exclusive use of e-cig <input type="checkbox"/> YES <input type="checkbox"/> NO If answered NO specify : <input type="checkbox"/> dual user, how long _____ Duration of smoking before e-cig start _____ If user of other tobacco product, specify _____		18. Use of E-cig containing <input type="checkbox"/> nicotine <input type="checkbox"/> nicotine+flavours, specify _____ <input type="checkbox"/> only flavours _____ <input type="checkbox"/> mixed substances _____		
20. Nicotine concentration (mg/ml): <input type="checkbox"/> rechargeable e-cig (refillable through the e-liquid bottle) _____ <input type="checkbox"/> disposable e-cig _____ <input type="checkbox"/> disposable cartridge _____		21. Duration of e-cig use <input type="checkbox"/> less than 1 month <input type="checkbox"/> 2-3 months <input type="checkbox"/> 4-6 months <input type="checkbox"/> more than 6 months	22. Restart e-cig use after AE <input type="checkbox"/> YES <input type="checkbox"/> NO <b>Symptoms returned</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
23. Is the electronic cigarette used at the time of the symptoms the same as normally used? <input type="checkbox"/> YES <input type="checkbox"/> NO Specify the brand _____ Sales point <input type="checkbox"/> specialized seller <input type="checkbox"/> pharmacy <input type="checkbox"/> internet <input type="checkbox"/> tobacconist <input type="checkbox"/> retail seller <input type="checkbox"/> other If answered NO it changed: <input type="checkbox"/> e-cig <input type="checkbox"/> cartridge <input type="checkbox"/> refill liquid <input type="checkbox"/> self-made e-cig <input type="checkbox"/> self-made/mixed liquid note _____ Specify the new brand (e-cig and/or liquid) _____ Sales point if different _____				
24. Medications, NRT and/or other products based on medicinal plants, homeopathic, food supplements etc. used at the time of the appearance of the AE <input type="checkbox"/> YES <input type="checkbox"/> NO If YES Specify _____ Dosage, route of administration and duration of use: _____				
25. Current or past relevant medical history (illnesses, allergies, alcohol use, drugs of abuse, etc.) _____ _____				
Manufacturer, importer, distributor				
26. _____				
27. date ..... Send this form to: Competent authority or market surveillance authority..... Address ..... Email..... Fax.....				

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

Reporting form of suspected adverse effects (AE) for electronic cigarette (e-cig) and refill liquid				
Patient individual data				
1. Initials or Record number	2. Year of birth	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F	4. Weight (kg)	5. Height (cm)
6. Ethnicity/race (optional)		7. Pregnancy <input type="checkbox"/> NO <input type="checkbox"/> YES, week _____ Breastfeeding <input type="checkbox"/> NO <input type="checkbox"/> YES		
Description of AE				
8. AE start (date) _____ <input type="checkbox"/> during e-cig use <input type="checkbox"/> after e-cig use, specify after how long: _____		9. Causes of AE <input type="checkbox"/> inhalation <input type="checkbox"/> e-cig explosion <input type="checkbox"/> poisoning from the refill liquid (by ingestion) <input type="checkbox"/> skin absorption <input type="checkbox"/> more intense use of e-cig, describe _____ Other _____		
10. Symptoms <input type="checkbox"/> throat irritation <input type="checkbox"/> coughing up of blood <input type="checkbox"/> headache <input type="checkbox"/> sore throat <input type="checkbox"/> bleeding form the nose <input type="checkbox"/> dizziness <input type="checkbox"/> dry mouth <input type="checkbox"/> anaphylaxis <input type="checkbox"/> vertigo <input type="checkbox"/> mouth ulcers <input type="checkbox"/> sweating <input type="checkbox"/> tremors <input type="checkbox"/> dry cough <input type="checkbox"/> abdominal pain <input type="checkbox"/> restlessness <input type="checkbox"/> laryngospasm <input type="checkbox"/> high blood pressure <input type="checkbox"/> tachycardia <input type="checkbox"/> asthma <input type="checkbox"/> vomiting <input type="checkbox"/> bradycardia <input type="checkbox"/> shortness of breath <input type="checkbox"/> skin rash <input type="checkbox"/> eye irritation <input type="checkbox"/> bronchospasm <input type="checkbox"/> nausea <input type="checkbox"/> nose irritation <input type="checkbox"/> chest pain <input type="checkbox"/> diarrhoea <input type="checkbox"/> burn and scalds <input type="checkbox"/> worsening of pre-existing conditions: _____ <input type="checkbox"/> other _____			11. If use of the e-cig was stopped did the AE stop? <input type="checkbox"/> NO <input type="checkbox"/> YES	
			12. Treatment of the AE <input type="checkbox"/> NO <input type="checkbox"/> YES Describe _____ _____	
			13. Seriousness of AE <input type="checkbox"/> required a visit to doctor <input type="checkbox"/> admitted to hospital <input type="checkbox"/> disability <input type="checkbox"/> life threatening <input type="checkbox"/> death	14. Outcome <input type="checkbox"/> discharged after doctor visit <input type="checkbox"/> recovered, how long _____ <input type="checkbox"/> fatal _____ (date) <input type="checkbox"/> unknown
15. Comments on causal relationships between e-cig and AE <input type="checkbox"/> certain <input type="checkbox"/> likely <input type="checkbox"/> possible <input type="checkbox"/> unlikely <input type="checkbox"/> unrelated <input type="checkbox"/> unknown note _____				
16. Describe any other detail (e.g. duration of the AE, complications/sequelae and any relevant laboratory results) _____ _____				
17. Exclusive use of e-cig <input type="checkbox"/> YES <input type="checkbox"/> NO If answered <b>NO</b> specify : <input type="checkbox"/> dual user, how long _____ Duration of smoking before e-cig start _____ If user of other tobacco product, specify _____		18. Use of E-cig containing <input type="checkbox"/> nicotine <input type="checkbox"/> nicotine+flavours, specify _____ <input type="checkbox"/> only flavours _____ <input type="checkbox"/> mixed substances _____		
20. Nicotine concentration (mg/ml): <input type="checkbox"/> rechargeable e-cig (refillable through the e-liquid bottle) <input type="checkbox"/> disposable e-cig _____ <input type="checkbox"/> disposable cartridge _____		21. Duration of e-cig use <input type="checkbox"/> less than 1 month <input type="checkbox"/> 2-3 months <input type="checkbox"/> 4-6 months <input type="checkbox"/> more than 6 months	22. Restart e-cig use after AE <input type="checkbox"/> YES <input type="checkbox"/> NO <b>Symptoms returned</b> <input type="checkbox"/> YES <input type="checkbox"/> NO	
23. Is the electronic cigarette used at the time of the symptoms the same as normally used? <input type="checkbox"/> YES <input type="checkbox"/> NO Specify the brand _____ Sales point <input type="checkbox"/> specialized seller <input type="checkbox"/> pharmacy <input type="checkbox"/> internet <input type="checkbox"/> tobacconist <input type="checkbox"/> retail seller <input type="checkbox"/> other If answered <b>NO</b> it changed: <input type="checkbox"/> e-cig <input type="checkbox"/> cartridge <input type="checkbox"/> refill liquid <input type="checkbox"/> self-made e-cig <input type="checkbox"/> self-made/mixed liquid note _____ Specify the new brand (e-cig and/or liquid) _____ Sales point if different _____				
24. Medications, NRT and/or other products based on medicinal plants, homeopathic, food supplements etc. used at the time of the appearance of the AE <input type="checkbox"/> YES <input type="checkbox"/> NO If <b>YES</b> Specify _____ Dosage, route of administration and duration of use: _____				
25. Current or past relevant medical history (illnesses, allergies, alcohol use, drugs of abuse, etc.) _____ _____				
Reporter information				
26. Title <input type="checkbox"/> general doctor <input type="checkbox"/> pharmacist <input type="checkbox"/> nurse <input type="checkbox"/> hospital doctor <input type="checkbox"/> consumer or his/her carer <input type="checkbox"/> medical specialist <input type="checkbox"/> other _____		27. Contact details Name + Surname Address Phone _____ Fax _____ E-mail _____		
28. date Send this form to fax.....email.....address.....				