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WP7 - D7.4

Report on a proposed system for the reporting of adverse effects

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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 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 ❑ M ❑ F	4. Weight (kg)	5. Height (cm)

6. Ethnicity/race (optional)

7. Pregnancy ❑NO ❑YES, week ____________
Breastfeeding ❑NO ❑YES

Description of AE

8. AE start (date) ____________________
❑ during e-cig use
❑ after e-cig use, specify after how long:
____

9. Causes of AE
❑ inhalation ❑ e-cig explosion ❑ poisoning from the refill liquid (by ingestion) ❑ skin absorption
❑ more intense use of e-cig, describe ____________________
Other ____________________

10. Symptoms

❑ throat irritation	❑ coughing up of blood	❑ headache
❑ sore throat	❑ bleeding form the nose	❑ dizziness
❑ dry mouth	❑ anaphylaxis	❑ vertigo
❑ mouth ulcers	❑ sweating	❑ tremors
❑ dry cough	❑ abdominal pain	❑ restlessness
❑ laryngospasm	❑ high blood pressure	❑ tachycardia
❑ asthma	❑ vomiting	❑ bradycardia
❑ shortness of breath	❑ skin rash	❑ eye irritation
❑ bronchospasm	❑ nausea	❑ nose irritation
❑ chest pain	❑ diarrhoea	❑ burn and scalds

❑ worsening of pre-existing conditions:____________________
❑ other____________________

11. If use of the e-cig was stopped did the AE stop?
❑ NO ❑ YES

12. Treatment of the AE
❑ NO ❑ YES
Describe____________________
____
____

13. Seriousness of AE
❑ required a visit to doctor
❑ admitted to hospital
❑ disability
❑ life threatening
❑ death

14. Outcome
❑ discharged after doctor visit
❑ recovered,
how long____________________
❑ fatal ____________________(date)
❑ unknown

15. Comments on causal relationships between e-cig and AE
❑ certain ❑ likely ❑ possibile ❑ unlikely ❑ unrelated ❑ 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 ❑ YES ❑ NO **If answered NO specify :**
❑ dual user, how long ____________________
Duration of smoking before e-cig start ____________________
If user of other tobacco product, specify____________________

18. Use of E-cig containing
❑ nicotine ❑ nicotine+flavours, specify____________________
❑ only flavours ____________________
❑ mixed substances ____________________

19. Nicotine concentration (mg/ml):
❑ rechargeable e-cig (refillable through the e-liquid bottle)
____
❑ disposable e-cig ____________________
❑ disposable cartridge____________________

20. Duration of e-cig use
❑ less than 1 month ❑ 2-3 months
❑ 4-6 months ❑ more than 6 months

21. Restart e-cig use after AE
❑ YES ❑ NO
Symptoms returned
❑ YES ❑ NO

22. Is the electronic cigarette used at the time of the symptoms the same as normally used? ❑ YES ❑ NO

Specify the brand ____________________ **Sales point** ❑ specialized seller ❑ pharmacy ❑ internet ❑ tobacconist ❑ retail seller ❑other

If answered NO it changed: ❑ e-cig ❑ cartridge ❑ refill liquid ❑ self-made e-cig ❑ self-made/mixed liquid **note**____________________

Specify the new brand (e-cig and/or liquid) ____________________ **Sales point if different** ____________________

23. Medications, NRT and/or other products based on medicinal plants, homeopathic, food supplements etc. used at the time of the appearance of the AE ❑ YES ❑ NO **If YES Specify** ____________________

Dosage, route of administration and duration of use: ____________________
____

24. Current or past relevant medical history (illnesses, allergies, alcohol use, drugs of abuse, etc.)
____
____

Manufacturer, importer, distributor

25.

26. 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 ❑ M ❑ F

4. Weight (kg)

5. Height (cm)

6. Ethnicity/race (optional)

7. Pregnancy ❑NO ❑YES, week ____________

Breastfeeding ❑NO ❑YES

Description of AE

8. AE start (date) ________________________

❑ during e-cig use

❑ after e-cig use, specify after how long: ____________________________

9. Causes of AE

❑ inhalation ❑ e-cig explosion ❑ poisoning from the refill liquid (by ingestion) ❑ skin absorption

❑ more intense use of e-cig, describe ____________________________

Other ____________________________

10. Symptoms

❑ throat irritation ❑ coughing up of blood ❑ headache

❑ sore throat ❑ bleeding form the nose ❑ dizziness

❑ dry mouth ❑ anaphylaxis ❑ vertigo

❑ mouth ulcers ❑ sweating ❑ tremors

❑ dry cough ❑ abdominal pain ❑ restlessness

❑ laryngospasm ❑ high blood pressure ❑ tachycardia

❑ asthma ❑ vomiting ❑ bradycardia

❑ shortness of breath ❑ skin rash ❑ eye irritation

❑ bronchospasm ❑ nausea ❑ nose irritation

❑ chest pain ❑ diarrhoea ❑ burn and scalds

❑ worsening of pre-existing conditions: ____________________________

❑ other ____________________________

11. If use of the e-cig was stopped did the AE stop?

❑ NO ❑ YES

12. Treatment of the AE

❑ NO ❑ YES

Describe ____________________________

13. Seriousness of AE

❑ required a visit to doctor

❑ admitted to hospital

❑ disability

❑ life threatening

❑ death

14. Outcome

❑ discharged after doctor visit

❑ recovered,

how long ____________________________

❑ fatal ____________________(date)

❑ unknown

15. Comments on causal relationships between e-cig and AE

❑ certain ❑ likely ❑ possibile ❑ unlikely ❑ unrelated ❑ 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 ❑ YES ❑ NO **If answered NO specify :**

❑ dual user, how long ____________________________

Duration of smoking before e-cig start ____________________________

If user of other tobacco product, specify ____________________________

18. Use of E-cig containing

❑ nicotine ❑ nicotine+flavours, specify ____________________________

❑ only flavours ____________________________

❑ mixed substances ____________________________

19. Nicotine concentration (mg/ml):

❑ rechargeable e-cig (refillable through the e-liquid bottle)

____

❑ disposable e-cig ____________________________

❑ disposable cartridge ____________________________

20. Duration of e-cig use

❑ less than 1 month ❑ 2-3 months

❑ 4-6 months ❑ more than 6 months

21. Restart e-cig use after AE

❑ YES ❑ NO

Symptoms returned

❑ YES ❑ NO

22. Is the electronic cigarette used at the time of the symptoms the same as normally used? ❑ YES ❑ NO

Specify the brand ____________________________ **Sales point** ❑ specialized seller ❑ pharmacy ❑ internet ❑ tobacconist ❑ retail seller ❑other

If answered NO it changed: ❑ e-cig ❑ cartridge ❑ refill liquid ❑ self-made e-cig ❑ self-made/mixed liquid **note** ____________________________

Specify the new brand (e-cig and/or liquid) ____________________________ **Sales point if different** ____________________________

23. Medications, NRT and/or other products based on medicinal plants, homeopathic, food supplements etc. used at the time of the appearance of the AE ❑ YES ❑ NO **If YES Specify** ____________________________

Dosage, route of administration and duration of use: ____________________________

____

24. Current or past relevant medical history (illnesses, allergies, alcohol use, drugs of abuse, etc.)

____

____

Reporter information

25. Title

❑ general doctor ❑ pharmacist ❑nurse

❑ hospital doctor ❑ consumer or his/her carer

❑ medical specialist ❑other ____________________________

26. Contact details

Name + Surname

Address

Phone Fax

E-mail

27. date……………………………

Send this form to fax…………………………………**email**…………………………………**address**…………………………………