Medicines & Healthcare products Regulatory Agency

MHRA

MHRA

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gov.uk/mhra

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Dear Reporter,

Thank you for completing a Yellow Card report on a suspected adverse reaction to an e-cigarette or vaping product. If you have not yet completed a Yellow Card report, please do this first and provide the reference number in the form below.

As you may be aware, in January 2020 the MHRA published a Drug Safety Update article relating to probable or possible vaping-induced lung injury. https://www.gov.uk/drug-safety-update/e-cigarette-use-or-vaping-reporting-suspected-adverse-reactions-including-lung-injury

Please find enclosed a tailored questionnaire asking specific clinical details, we would greatly appreciate if you could return this form with as much details as you are able to. **This form can be posted to "Freepost Yellow Card" or alternatively it can be emailed to yellow.card@mhra.gov.uk.**

Please include any other information that you consider to be relevant and remove patient personal identifiers such as name and date of birth from all information supplied, where possible. If the lung injury experienced resulted in a fatality, please provide a copy of the post-mortem report where available.

All information provided is held in strict confidence and handled in line with our Yellow Card Privacy Policy, which can be found at https://yellowcard.mhra.gov.uk/privacy-policy/. If you wish to request a copy of the information we hold on your case or a copy of your report as it appears in our database, please write to us at the address above or email yellow.card@mhra.gov.uk citing your case reference number and details of your request.

Your contribution to the UK's Adverse Reaction Reporting Scheme is greatly appreciated. This provides an important early warning of previously unrecognised adverse effects which allows us to take appropriate action to improve the safe use of e-cigarettes.

Yours sincerely,

Vigilance and Risk Management of Medicine
MHRA

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Probable/ Possible e-cigarette associated lung injury Surveillance: Patient form

Does this case meet the criteria for:

Probable e-cigarette or vaping associated lung injury ☐
Possible e-cigarette associated lung injury ☐

Yellow Card reference number (please fill in this form only once Yellow Card has been submitted)

Patient details

1. Date of admission to hospital:
2. Date of admission to ICU (if applicable):
3. Suspected underlying pathology

(eg: hypersensitivity pneumonitis, lipoid pneumonia):

4. Is the patient deceased ☐ Yes ☐ No.
5. Is the post-mortem report available: ☐ Yes ☐ No. If yes, please send report to yellowcard@mhra.gov.uk or post to Freepost Yellow Card including reference number

Smoking history (combustible cigarettes)

6. Is the patient a current smoker? ☐ Yes ☐ No
7. If the patient is a previous smoker, please provide stopping date: _____
8. Please provide number of cigarettes smoked a day: _____
9. Please provide total duration of smoking: _____
10. Does the person smoke cannabis? ☐ Yes ☐ No

E-cigarette product details

[E-cigarette use or vaping is defined as the use of vaping devices which produce vapour for inhalation by heating liquid which may contain nicotine (e-cigarettes), be nicotine-free or contain THC, CBD or other substances.]

11. Brand name of device(s) used

Please provide names here for all devices used:

12. Brand name of e-liquid(s):

Please provide names here for all e-liquids used:

13. Flavour of e-liquid(s):

Please provide names here for all flavours used:

14. Does the e-liquid used contain nicotine? ☐ Yes ☐ No

15. Did the patient report use of other substances in their e-cigarette:

Tetrahydrocannabinol (THC)	☐
Cannabidiol (CBD)	☐
Other cannabinoids (e.g., K2 or spice, cannabis, hash oil, dank vapes)	☐
Vitamin E acetate	☐
Other, please specify	☐
None reported	☐

16. Strength of substances (mg/mL):

Nicotine	
Tetrahydrocannabinol (THC)	
Cannabidiol (CBD)	
Other, please specify	

17. What technique did the patient use to inhale the vapour?

Mouth to lung	☐
Direct to lung	☐
Not known	☐

18. Date of last e-cigarette product usage (DD/MM/YY) _____

19. Number of days/ weeks/ months using e-cigarettes (state units) _____ or ☐ Not known

20. Is it possible to obtain a sample of the product? ☐ Yes ☐ No

If yes, please confirm that you give permission for us to provide your contact details to local Trading Standards to facilitate sample testing. Yes, I give permission for my details to be shared ☐

Please tick all that apply: ☐ e-liquid (pod or bottle) ☐ tank ☐ device ☐ other, please specify_____

21. Is it possible to obtain a photo of the product ☐ Yes ☐ No. If yes, please send with this form.

22. What was the approximate frequency of product use (please select the most appropriate):

Daily	☐
At least weekly	☐
At least Monthly	☐
Less than monthly	☐

23. Amount of e-liquid used per day (mLs)

0-5 mL	☐
6-10 mL	☐
11-15mL	☐
>15mL	☐
Other, please specify:	☐

24. Was there possible environmental or second-hand exposure to e-cigarettes? ☐ Yes ☐ No

    a. Number of e-cigarette users in household: _____

    b. Relationship of e-cigarette users to patient: _____

25. Type of device used: ☐ Disposable ☐ Refillable ☐ Voltage variable ☐ Pod based Other, please specify _____ ☐ Not known

26. How and where was the product purchased

Online	☐ Yes ☐ No	Please state website:
Retail	☐ Yes ☐ No	Please state business and address:
Black market	☐ Yes ☐ No	Please provide details, if known:
Home made	☐Yes ☐ No	Please provide details, if known:

Clinical features

27. Symptoms

Respiratory	☐ Yes ☐ No	Date of onset: Details:
Gastrointestinal	☐ Yes ☐ No	Date of onset: Details:
Any other clinical presentation	☐ Yes ☐ No	Date of onset: Details:

28. History of foreign travel ☐ Yes ☐ No? If Yes, was travel related illness excluded, eg: malaria, typhoid fever, Middle Eastern Respiratory Syndrome coronavirus (MERS) ☐ Yes ☐ No

If yes, please provide details:

29. History of inhalational exposure to toxic substances eg: cleaning products, pest fumigation etc? ☐ Yes ☐ No

If yes, please provide details:

30. History of occupational exposure to toxic substances eg: asbestos, silica, heavy metals etc or occupational exposure to e-cigarette liquid eg: manufacturing? ☐ Yes ☐ No

If yes, please provide details:

31. Was invasive ventilatory support required: ☐ Yes ☐ No.

32. Were criteria for Acute Respiratory Distress Syndrome (ARDS) met: ☐ Yes ☐ No

33. Other relevant pre-existing conditions:

Cardiac eg: ischaemic heart disease, cardiac failure	☐ Yes ☐ No	Details:
Respiratory eg: asthma, Chronic Obstructive Pulmonary Disease (COPD), obstructive sleep apnoea	☐ Yes ☐ No	Details:
Endocrine eg: diabetes	☐ Yes ☐ No	Details:
Other (please specify)	☐ Yes ☐ No	Details:

Investigations

34. Serology

Raised inflammatory markers (eg: ESR, CRP)	☐ Yes ☐ No	Details (eg: peak levels and date)
White blood cell count	☐ Yes ☐ No	Details (eg: peak levels and date)
Transaminases and liver function tests	☐ Yes ☐ No	Details (eg: peak levels and date)
Autoimmune markers (eg: ANA, ANCA, anti-Rho / anti-La, Rh factor, dSDNA)	☐ Yes ☐ No	Details (eg: peak levels and date)
IgG against avian antigens (eg: screen for pigeon or budgerigar fancier's lung)	☐Yes ☐ No	Details (eg: peak levels and date):
Other		Please specify:

35. Microbiology

Blood culture	☐ Yes ☐ No	Please enter organism(s) if positive:
Urinary antigen for the following:		
Streptococcus pneumoniae	☐ Yes ☐ No	Result
Legionella pneumophilia	☐ Yes ☐ No	Result
Positive result from respiratory specimen for PCR for the following: If yes, please also specify site obtained (eg: sputum, nasopharyngeal swab, bronchoalveolar lavage)		
Streptococcus pneumoniae	☐ Yes ☐ No	Result: Site obtained:
Haemophilus influenzae	☐ Yes ☐ No	Result: Site obtained:
Staphylococcus aureus	☐ Yes ☐ No	Result: Site obtained:
Klebsiella pneumoniae	☐ Yes ☐ No	Result: Site obtained:
Bordetella pertussis/ parapertussis	☐ Yes ☐ No	Result: Site obtained:
Legionella pneumophilia	☐ Yes ☐ No	Result: Site obtained:
Pneumocystis jirovecii	☐ Yes ☐ No	Result: Site obtained:

Chlamydophila pneumoniae	☐ Yes ☐ No	Result: Site obtained:
Mycoplasma pneumoniae	☐ Yes ☐ No	Result: Site obtained:
Influenza A/B	☐ Yes ☐ No	Result: Site obtained:
Parainfluenza 1/2/3/4	☐ Yes ☐ No	Result: Site obtained:
Human rhinovirus/ enterovirus	☐ Yes ☐ No	Result: Site obtained:
Coronavirus	☐ Yes ☐ No	Result: Site obtained:
Metapneumovirus	☐ Yes ☐ No	Result: Site obtained:
Bocavirus	☐ Yes ☐ No	Result: Site obtained:
Adenovirus	☐ Yes ☐ No	Result: Site obtained:
Respiratory syncytial virus	☐ Yes ☐ No	Result: Site obtained:

Other microbiology

Fungal eg: Aspergillus species, Candida species, Cryptococcus species, Histoplasma.	☐ Yes ☐ No	Date: Details: Results:

Mantoux test or Interferon gamma release assay (IGRA) for Mycobacterium tuberculosis	☐ Yes ☐ No	Date: Details: Results:
Other opportunistic eg: Pneumocystis jirovecii	☐ Yes ☐ No	Date: Details: Results:
p24 antigen or fourth generation testing for Human Immunodeficiency Virus (HIV) 1 or 2	☐ Yes ☐ No	Date: Details: Results

36. Radiology

Provide results from most significant changes seen:

Chest X ray eg: bilateral opacities	☐ Yes ☐ No	Results:
CT scan eg: bilateral ground glass changes	☐ Yes ☐ No	Results:

37. Spirometry/ Lung function testing

Provide results from most significant values seen:

Forced Expiratory Volume in 1 second (FEV1)	☐ Yes ☐ No	Predicted normal value	% of predicted normal value	
Forced Vital Capacity (FVC)	☐ Yes ☐ No	Predicted normal value	% of predicted normal value	
FEV1/ FVC	☐ Yes ☐ No	Predicted normal value	% of predicted normal value	
Peak Expiratory Flow Rate (PEFR)	☐ Yes ☐ No	Predicted	Actual	

38. Toxicology

Please select Yes for positive result, and provide specimen this was derived from.

Tetrahydrocannabinol (THC)	☐ Yes ☐ No	Date: Results: Specimen (eg: blood, urine):
Cannabidiol (CBD)	☐ Yes ☐ No	Date: Results: Specimen (eg: blood, urine):
Other cannabinoid	☐ Yes ☐ No	Date: Results Specimen (eg: blood, urine):
Other substance	☐ Yes ☐ No	Please specify: Results: Specimen (eg: blood, urine):

39. Echocardiography ☐ Yes ☐ No, if Yes, please provide results and reference ranges:
Provide results from most significant values seen:

Left ventricular outflow tract velocity time integral	
Left ventricle size	
Ejection fraction using Simpsons method	
Right ventricle size	
Tricuspid annular plane systolic excursion (TAPSE)	
Other (please specify) or any other details	

Specimens obtained

Biopsy	☐ Yes ☐ No	Specify site: Date: Results:

40. Based on clinical presentation and investigations, please confirm the alternative causes excluded:

Infectious	☐ Yes ☐ No	Basis for exclusion
Cardiac (eg: acute coronary syndrome, tachyarrhythmias, acute valvular rupture, bacterial endocarditis)	☐ Yes ☐ No	Basis for exclusion
Autoimmune/ connective tissue (eg: SLE, sarcoidosis, Wegener's granulomatosis, Sjogren's syndrome)	☐ Yes ☐ No	Basis for exclusion
Malignant	☐ Yes ☐ No	Basis for exclusion
Other, please specify:		Basis for exclusion:

Management

41. Were antibiotics used ☐ Yes ☐ No
42. Were antivirals used ☐ Yes ☐ No
43. Were corticosteroids used ☐ Yes ☐ No
44. Other, please specify_____
45. If intubation was required, please provide:

Duration of intubation: Ventilatory mode (eg: pressure controlled, volume controlled, high frequency oscillation): Maximum pressures and tidal volumes:

Outcome

46. Date of discharge from ICU (DD/MM/YY):_____

47. Date of discharge from hospital (DD/MM/YY):_____

48. Ongoing conditions at time of discharge:

Please provide details:

49. Medications at time of discharge:

Please provide details:

50. Date of death (if applicable, DD/MM/YY):_____