|  |  |
| --- | --- |
|  | **MHRA**  10 South Colonnade  Canary Wharf  London  E14 4PU  United Kingdom  gov.uk/mhra  January 2020 |

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**](mailto: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](mailto: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

**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): |

1. Is the patient deceased  Yes  No.
2. Is the post-mortem report available:  Yes  No. If yes, please send report to [yellowcard@mhra.gov.uk](mailto:yellowcard@mhra.gov.uk) or post to Freepost Yellow Card including reference number

*Smoking history (combustible cigarettes)*

1. Is the patient a current smoker?  Yes  No
2. If the patient is a previous smoker, please provide stopping date: \_\_\_\_\_\_\_\_\_\_
3. Please provide number of cigarettes smoked a day: \_\_\_\_\_\_\_\_\_\_\_\_
4. Please provide total duration of smoking: \_\_\_\_\_\_\_\_\_\_\_\_
5. 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.]*

1. Brand name of device(s) used

|  |
| --- |
| Please provide names here for all devices used: |

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

|  |
| --- |
| Please provide names here for all e-liquids used: |

1. Flavour of e-liquid(s):

|  |
| --- |
| Please provide names here for all flavours used: |

1. Does the e-liquid used contain nicotine? ☐ Yes ☐ No
2. 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 |  |

1. Strength of substances (mg/mL):

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

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

|  |  |
| --- | --- |
| Mouth to lung |  |
| Direct to lung |  |
| Not known |  |

1. Date of last e-cigarette product usage (DD/MM/YY) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Number of days/ weeks/ months using e-cigarettes (state units) \_\_\_\_\_\_\_\_\_\_\_\_ or ☐ Not known
3. 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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is it possible to obtain a photo of the product   Yes  No. If yes, please send with this form.
2. What was the approximate frequency of product use (please select the most appropriate):

|  |  |
| --- | --- |
| Daily |  |
| At least weekly |  |
| At least Monthly |  |
| Less than monthly |  |

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

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

1. Was there possible environmental or second-hand exposure to e-cigarettes?  Yes  No
   1. Number of e-cigarette users in household: \_\_\_\_\_\_\_
   2. Relationship of e-cigarette users to patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Type of device used:  Disposable  Refillable  Voltage variable  Pod based Other, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Not known
3. 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*

1. 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: |

1. 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: |

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

|  |
| --- |
| If yes, please provide details: |

1. 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: |

1. Was invasive ventilatory support required:  Yes  No.
2. Were criteria for Acute Respiratory Distress Syndrome (ARDS) met:  Yes  No
3. 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*

1. 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: |

1. 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 |

1. 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: |

1. 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 |  |

1. 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): |

1. 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: |

1. 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*

1. Were antibiotics used  Yes  No
2. Were antivirals used  Yes  No
3. Were corticosteroids used  Yes  No
4. Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. 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*

1. Date of discharge from ICU (DD/MM/YY):\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Date of discharge from hospital (DD/MM/YY):\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Ongoing conditions at time of discharge:

|  |
| --- |
| Please provide details: |

1. Medications at time of discharge:

|  |
| --- |
| Please provide details: |

1. Date of death (if applicable, DD/MM/YY):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_