Medicines & Healthcare products
Regulatory Agency

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[redacted]

29th August 2023

Dear [redacted]

FOI 23/561 – Request for data on death and serious injury from misuse of oxygen supplies

Thank you for your Freedom of Information request dated 21st July 2023 where you asked for data on deaths or serious incidents due to failures of oxygen concentrators, misuse of cylinders or faulty cylinders, as well as information on published reports, studies, or statistical analyses available on this subject.

It may be helpful for us to explain that while oxygen is regulated as a medicine, oxygen concentrators and regulators used with oxygen cylinders are regulated as medical devices and therefore are subject to different regulations including incident reporting requirements. This also impacts how and where the MHRA publishes data on adverse events for oxygen regulators.

We have searched our databases holding incident reports for medical devices. The MHRA have received 99 serious or fatal adverse incident reports between 2006 and 2022 in relation to oxygen concentrators and regulators for gas cylinders. Of those 99 incident reports, X concern misuse of the device stated as a user error in the investigation findings. Please note however that this information is only available from 2006 onwards in our database and is not always provided by the reporter of the incident, and therefore may not be complete. This data includes reports received from manufacturers, healthcare professionals and members of the public. The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.

Please see table 1 below which provides details on the number of reports received per year.

Table 1: Number of serious or fatal adverse incident reports received for oxygen concentrators and regulators for gas cylinders.

Year received	Number of incidents*	Number of incidents related to misuse
2003	1	-
2004	4	-
2005	3	-
2006	5	1
2007	2	0

2008	6	5
2009	1	0
2010	2	0
2011	5	2
2012	2	1
2013	2	2
2014	8	2
2015	3	0
2016	7	1
2017	9	1
2018	7	1
2019	5	1
2020	9	0
2021	19	2
2022	9	1

*the total number of incidents including those relating to misuse.

You may note the increased reporting in 2021 compared to other years which may be related to increased use of oxygen during the pandemic.

Please also note the following considerations in relation to the data provided:

- There may be some duplication of reports across medical devices data and what is held for medicines via the published information linked below.
- this information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- reports do not necessarily represent an individual patient and incident. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of device and on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate when interpreting the data, it is important to note that the number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.
- the inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.
- adverse incident reports by members of the public are voluntary but play a substantial part in the successful operation of the vigilance system. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system.
- in addition, the use of our Yellow Card scheme by healthcare professionals and members of the public are voluntary and therefore do not provide absolute adverse event figures.

As you may be aware there has been a national investigation into the safety of oxygen cylinders by Health Services Safety Investigations Body (HSSIB). The final report can be found in the following link:
Design and safe use of portable oxygen systems — HSIB
You can also find information in the Patient Safety Alerts published by NHS England in the following links:

- NHS England » Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders
- NHS England » National Patient Safety Alert – Use of oxygen cylinders where patients do not have access to medical gas pipeline systems

You can find details of incidents related to medicines, including oxygen, in the interactive Drug Analysis Profiles (iDAPs) which are available on our website. These list all the reports that have been submitted

to the Yellow Card scheme in association with medicines: What is being reported | Making medicines and medical devices safer (mhra.gov.uk). As with all medicines, vaccines and medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/ Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.

We hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency