



# Medicines & Healthcare products Regulatory Agency

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Our Ref: **FOI2025/00001**

24 January 2025

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 2 January. You wrote:

*Any documents (including email or other communications) in relation to safety incidents involving modular seating systems for disabled children including those manufactured by: (i) Schuchmann; (ii) Tendercare; (iii) Jenx; (iv) Rifton; (v) Leckey; (vi) Everday; (vii) Mygo; (viii) Squiggles; (ix) R82 by Etac; and (x) Liwcare.*

*This should include (but not be limited to) communications between the MHRA and: (a) the manufacturers listed at (i) to (x); (b) UK local authorities; and/or (c) the NHS.*

*To the extent such documents contain personal data or sensitive personal data of third parties please can these be provided with appropriate redactions to protect such information (and not withheld).*

## MHRA Response

We are unable to deal with your Fol request without clarification of the information you seek. The reason for this we cannot use “modular seating systems” as a search term and therefore require further descriptions of these medical devices to ensure that your request can be properly met.

Under Section 16 of the Fol Act we should assist you in helping you focus your request. The overall request is broad and does not cover specific a time period, you may wish to narrow the focus of your request and consider the following:

- The specific types of devices/systems you are requesting (e.g. wheelchairs).
- The specific subject matters or the types of incidents you are seeking.
- A defined time frame for when incidents may have occurred.

As part of this Fol review, we conducted preliminary searches for information that you may find useful, limiting the time period to two years (from 01/01/2023 to 14/01/2025). We undertook searches using internationally agreed terminology (Global Medical Device Nomenclature/GMDN) using the terms (65190 and 45887 - *Wheelchair head/trunk support, custom-made and prefabricated*) which showed that MHRA held no details of safety incidents on these types of devices.

We identified two Field Safety Notices (FSNs) published by Jenx Limited involving medical devices that could be interpreted as a modular system for disabled children, and an additional FSN from a different manufacturer regarding a wheelchair used in children. Please see the summaries details below, and a copy of each FSN attached to this letter.

- *Device Name(s):* **Ly-on**  
*Manufacturer:* Jenx Limited  
*FSN Reference:* FSN-016A and FSN-016B  
*Summary:* High risk of the device being used incorrectly, by allowing weight to be applied to the side rail causing the locking mechanism to fail.  
*GMDN Code:* 32266 - Massage table/couch, non-powered, non-portable
- *Device Name(s):* **Supine 2 and Multistander 2**  
*Manufacturer:* Jenx Limited  
*FSN Reference:* FSN-015A  
*Summary:* Potential for device to get stuck in the vertical position and lose pressure in the lifting arm.  
*GMDN Code:* 61702 - Electric stander
- *Device Name(s):* **Bugzi Wheelchair**  
*Manufacturer:* Medical engineering resource unit (MERU)  
*FSN Reference:* FSN-01-2023  
*Summary:* Non-compliance to relevant standards triggering a recall.  
*GMDN Code:* 41875 - Electric-motor-driven wheelchair, occupant-controlled

The information referenced above is available in the public domain and can be found here: [Alerts, recalls and safety information: medicines and medical devices - GOV.UK](#).

Please be aware that specific manufacturer documents and communications, may be commercially sensitive and exempt from release under Section 43(2) of the FoI Act. As required by the FoI Act the use of this exemption will require the public interest for and against disclosure to be assessed.

We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

We recommend that you familiarise yourself with the Information Commissioners Office guidance on how to submit an FOI to a public authority. We have provided these links below to aid in future requests:

<https://ico.org.uk/for-the-public/official-information/preparing-and-submitting-your-information-request/>

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
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## **Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

## **Re-use of our information**

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>