Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]
By email: [redacted]

04 April 2024

FOI **24/239**

Dear [redacted],

Thank you for your information request, dated **29 February 2024**, in response to FOI 24/139, where you asked for:

"*A timeline of key dates in relation to the safety review of the Magnetic Expansion Control System (MAGEC).*

In addition, you also asked for *'how learnings have been taken from this situation to better inform patients and parents on updates to ongoing safety reviews.'*

In regard to your first request, please find attached a timeline of the key milestones and dates during the MHRA investigation of the MAGEC system. The timeline also includes links to publicly available documents. Please note that there is some information within the timeline that we consider to be exempt and has been redacted. The redactions have been applied under the following exemption:

- Section 43(2) Section 43(2) (Commercial interests) of the Freedom of Information (FOI) Act. Section 43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any overriding public interest argument in releasing information into the public domain that may be of interest to competitors and could cause commercial harm to NuVasive Specialised Orthopedics. Please note that in line with the guidance from the Information Commissioner's Office (ICO) we consider a response or disclosure under FOI to be made to the world at large, which in due course will be published (in a redacted form to remove personal information) on our website. So whilst we are not referring to

you as a competitor, any response or information we give to you or anyone else via FOI will become publicly available.

It may also be helpful for us to provide some supporting information to help interpret the timeline. Please see below.

- As you may be aware, the MHRA regulate medical devices, such as the MAGEC system, in the UK with the aim of ensuring that they meet the standards set out in the UK Medical Devices Regulations 2002. As part of our regulatory function, we perform market surveillance of medical devices on the UK market and can take decisions over the marketing and supply of devices in the UK. However, it is important to note that the MHRA do not authorise medical devices. This process is carried out by a Notified Body who conduct a conformity assessment of the device before it is placed onto the market. This process usually includes a review of the manufacturers quality management system and technical documentation related to the safety and performance of the device. Therefore, as part of our investigation we informed the Notified Body (DQS) of our initial findings from our investigation.
- The Spinal Expert Advisory Group (SEAG) is an independent MHRA expert advisory group which was established to provide advice on issues relating to the investigation conducted by the MHRA on the safety and performance of the MAGEC system. The SEAG included consultant orthopaedic surgeons and experts in orthopaedic engineering.
- Please note that as the MHRA Expert Advisory Groups (EAG) provide independent advice to the MHRA, manufacturers are not included in the EAG, therefore, NuVasive Specialised Orthopedics were not invited to participate in the SEAG.
- At the SEAG meeting on the 13 July 2022, it was agreed that the UK suspension of MAGEC could be lifted if the manufacturer met a number of conditions. These conditions were finalised via written correspondence with SEAG members before being sent to the manufacturer for agreement.
- At all points during the investigation, we worked closely with NuVasive Specialised Orthopedics and our SEAG to ensure that our concerns regarding the safety and performance of the device had been addressed. The conditions agreed to return the MAGEC system to the UK market allow us to proactively monitor the long-term safety and performance of the device. The latest DSI published on the 12 March 2024 concluded that we are satisfied that the modified MAGEC X can now be used in the UK.

In relation to your second request, the MHRA do not currently hold any documentation on the learnings that have been taken from this situation. However, I would like to assure you that we will review our investigation of MAGEC and our safety communications to see where we could provide more information to patients and their parents and carers at an earlier point in time. Following, your review of the attached timeline, we would be grateful for any feedback you may have, where you

feel an update would have been beneficial. This will then feed into our lessons learned review.

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOI Team
Safety & Surveillance
Medicines & Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London, E14 4PU