Medicines & Healthcare products Regulatory Agency

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

[redacted]

13 November 2023

Dear [redacted]

FOI 23/802

Thank you for your email dated, 16 October 2023, concerning stem cell therapy for the treatment of keratoconus.

You have enquired '…….are you able to give any indication at all about when or if this treatment might be approved/licensed in the UK for the treatment of something like this?'

[redacted]

We do not know for sure the US product to which you refer, however, unfortunately, the type of information you have requested would be commercially sensitive, and as such we cannot confirm or deny whether we have received any applications or at what stage any applications may be. We consider this information to be exempt under Section 41(2) (Information provided in confidence) and Section 43(3) (Commercial interests) of the Freedom of Information (FOI) Act.

Please note that we do not solicit applications for new medicines, or the addition of new indications to currently authorised medicines, and we do not conduct our own product development. Any company would need to approach us to apply for a Marketing Authorisation.

Section 41 is an absolute exemption, and no consideration of the public interest is required, except to state that we would consider confirming or denying whether we have received any applications for a particular product would be an actionable breach of confidence. Section 43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a company is close to obtaining a

marketing authorisation or not. 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.

If you believe there is a company which is developing such a treatment then you may wish to contact them directly, as they may be willing to provide an update on their regulatory position in the UK.

We would like to make you aware that UK medicines legislation does recognise that there are situations where a product which is not authorised in the UK may be required for an individual patient. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product under certain circumstances, which includes the importation of such medicines to the UK. In the interest of public health, the exemption is narrowly drawn because unlicensed medicines or "specials", unlike licensed medicinal products, may not have been assessed by us here at the MHRA against the criteria of safety, quality and efficacy. We have published guidance about this process, and you may wish to discuss this further with your son's doctor.

We now consider this FOI request closed. If you have a query about this letter, please contact the MHRA FOI Licensing mailbox using the email address listed below.

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 2 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 are not content with the outcome of the internal review, you 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,

The FOI Licensing Team
Healthcare Quality and Access

Email: FOILicensing@mhra.gov.uk