FOI 23/273 - Phillips Sumika Material Safety Data Sheet

REQUEST MADE: 11 April 2023

MHRA RESPONSE
16 April 2023

Dear

Thank you for your request for information submitted under the Freedom of Information Act, which was as follows:

- **Please can you confirm if you received the Phillips Sumika Material Safety Data Sheet in 2008 for full transparency of the nature of the PP product from C.R.Bard and any and all C.R.Bard UK agents and doctors that were supplying hospitals in the UK to implant patients with their PP medical devices**
- **According to MHRA vigilance reports did C.R.BARD and any and all C.R.BARD agents/doctors submit a copy of Phillips Sumika Material Safety Data Sheet which you should have received in 2008?**

MHRA has no record of having received the Phillips Sumika Material Safety Data Sheet in 2008. A review of vigilance reports received from CR Bard and of their representatives relating to surgical mesh devices during the time period 2006 to 2014 has been undertaken. We confirm that the Philips Sumika Material Safety Data Sheet was not submitted to MHRA in any of these vigilance reports.

Additional background information which you may find useful:

In the UK, the MHRA does not perform the pre-market assessment for conformity against the UK Medical Device Regulations 2002. This function and responsibility is held by third party assessment bodies known as Approved Bodies. Prior to the UK leaving the EU, these bodies were known as Notified Bodies, which still operate in the EU today. A successful assessment for conformity by the relevant Body results in a certificate being issued to the manufacturer of the device, permitting them to place the CE mark on the device. Medical devices which bear the CE mark may be freely marketed in the EU and UK.

Whilst the Material Safety Data Sheet is an example of a document we would expect the manufacturer of a medical device to hold in their dossier supporting the device's conformity with the medical device regulations, and therefore be available for review by the conformity assessment body, it is not a document which would have been routinely submitted to MHRA.

The regulatory framework in the UK and EU is different to that of the USA, where the equivalent organisation to the MHRA, the FDA, does have direct responsibility for confirming a manufacturer has evidence of compliance with the USA medical device regulations to place a medical device on the market in the USA.

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

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU