Medicines & Healthcare products Regulatory Agency

MHRA

Medicines and Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

gov.uk/mhra

Ms Joanna Wood
Independent Medicines and Medical Devices Safety Review
Rm 3.25b Shepherd's House
King's College London
London
SE1 1UL

04 July 2019

Dear Ms Wood

Thank you for your email of 20 June enclosing a transcript of several passages you have identified from the evidence given to the review by Ms Joanna Davies of the Mesh UK Charitable Trust.

I am grateful for the opportunity to provide a response which is set out in Annex 1.

I would be happy to provide further clarification, if that would be helpful.

Your sincerely

Graeme Tunbridge
Group Manager, Devices – Regulatory Affairs

Annex 1

Passage 2 Interaction of the user and safety of devices

We agree that one of the main safety factors is interaction of a user with a medical device. The Medical Devices Directive and the new EU Medical Devices Regulations lay down essential requirements (set out in Annex I) relating to the design and manufacture of medical devices so that the risk of use error[1] is reduced as far as possible and reasonably foreseeable misuse is managed or controlled. This includes a consideration of the technical knowledge, experience, education and training, and where applicable the medical and physical conditions of intended users (that is whether they are lay persons, professional or disabled).

It forms part of a risk management (like ISO 14971) process the manufacturer must undertake to comply with the leglislation. It may also include applying human factors/usability standards to medical devices and we have published guidance on the importance of applying human factors to medical devices, so they are designed and optimised to minimise patient and user safety risks.

The essential requirements also require manufacturers to provide certain information on the device, which is needed to use it safely and properly, taking account of the training and knowledge of the potential users. This information is set out on the label and/or within the instructions for use and includes (amongst other requirements):

- details on the safe and proper use of the device; and
- any warning and precautions to be taken.

The manufacturer may specify the device may only be used by certain groups or individuals (e.g. for use by healthcare professionals only), but they can not necessarily control *how* that person uses it. We have issued 'Off-label use of a medical device' guidance which states users should follow the manufacturer's instructions for use. If these devices are used in any other way, it would likely be considered 'off-label use' and the users in question may become liable for civil claims for damages from injured patients or families if something goes wrong with the device.

Passage 2 MHRA post market surveillance reports

We have taken this to mean reference to our annual report on devices adverse incidents which shows key statistics and significant actions taken in that year. A summary of anonymised medical device incident data (2011-2013) was published in April 2014 and had improvements to content and format to reflect developments to how we worked. It replaced the annual report. These are found on archived webpages.

As outlined in our response to IMMDSR follow up questions on 19 April, the MHRA aims to be as transparent as legally possible. We have worked hard towards greater transparency and we are aiming to introduce a UK transparency scheme by 2020.[2] Work also continues to provide anonymised incident data on our website, and we anticipate a mesh dedicated webpage to be published this summer to show incident data for mesh to treat stress urinary incontinence and pelvic organ prolapse. In the meantime, we are always happy to answer any request for anonymised data.

---

[1] Act or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator of the medical device. MEEDEV 2.12-1 Rev 8

[2] http://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20%20Evidence%20Submitted%20Following%20Oral%20Hearings.pdf page 178

Passage 3 Expertise within the Agency

We have met with representatives of Mesh UK Charitable Trust and provided several responses to them on request. We are sorry to hear Ms Davies felt these interactions did not meet her expectations.

To be an effective regulator we draw on people with a wide range of skills, experience and background to engage with everyone and to provide authoritative advice and information across the huge numbers of devices we are responsible for.

We are recognised globally as an authority in its field and the Agency plays a leading role in protecting and improving public health. For example, our work in agreeing the new EU Regulations to strengthen the regulatory framework demonstrates our understanding of the regulations and the system we are part of.

Our strength is our diversity across all levels of staff. If we are to be successful and credible in managing risk across the system, highly qualified and professionally recognised people are needed by us. So, we continue to attract, employ, retain and develop our staff to ensure we meet the needs of all our stakeholders.

Passage 4 Regulation of devices (staples and other implantable devices) and testing with mesh

A surgeon may use different types of staples or sutures to close incisions after mesh procedures or anchors as mesh fixation devices to remain in the body. They are all medical devices, and like mesh they must comply with the requirements of the legislation described in Passage 2 above.

They are considered to be implantable devices under the legislation if they are intended to remain in the body for at least 30 days or if they are totally introduced into the body and are intended to remain there. In either case they will require an appropriate assessment by an independent third-party organisation, called a Notified Body (NB) who will issue relevant certification to the manufacturer, providing the device meets the requirements set out in the legislation.

The device classification ranging from low to high risk will depend on its intended use, degree of invasiveness and time of contact with the body. Like mesh these devices are generally regarded as medium or high risk. If they are packaged as a system with the mesh, they can also be classified with the highest device class in that system – likely to be the mesh device.

This classification system reflects the appropriate conformity assessment route to be taken to obtain a CE mark. It does not change the standards of safety and performance the anchors, staples or sutures must meet.

The essential requirements in Annex I of the Directive and new EU Regulations requires manufacturers to make sure devices that are intended for use with other devices are safe and do not impair the performance of either device. This will include relevant compatibility test data and we would expect this information to be in the technical file of the device.