Medicines & Healthcare products Regulatory Agency

MHRA

Ms Joanna Wood
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Dear Ms Wood

Re: Sling the Mesh transcript

Thank you for your email of 27 June enclosing a transcript of several passages you have identified from the evidence given to the review by Ms Michelle Moffatt of Sling The Mesh.

In our written evidence to the IMMDS Review[1], we have provided an extensive response to several areas covered in the transcript passages you have identified including our actions to address the concerns of women, our role and relationships in the regulatory system, and strengthening it. Furthermore, our emails dated 18 April and 08 May provide information on the FDA action relating to transvaginal surgical mesh for pelvic organ prolapse (POP) and our response to this.

However, there are some points on which I would like to provide a response to.

Passage 1 - Patient safety and the Regulations
Patient safety is at the heart of the regulations and is our highest priority. We will ensure patient concerns are acted upon appropriately, and as swiftly as possible. As an effective regulator our responsibility is to provide up-to-date and authoritative information to help patients and healthcare professionals make the best choices for each individual.

The MHRA is of the view that the principles of the current regulatory system are fit for purpose, but we have also been clear about the need to adapt and update the EU legislation in this area to reflect technological developments and ensure that everyone involved is acting to the same high standards.

The UK Government has actively championed the new Medical Devices Regulation 2017/745 (MDR) and *in vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) to ensure that our priority areas were reflected in the new legislation and we were clear that this will result in a significant strengthening of the regulatory framework. The new Medical Device Regulations, which came into force in May 2017[2] provide more rigorous and specific demands on manufacturers in terms of both pre-market evidence and post-market surveillance to ensure that there is sufficient scrutiny of these devices in both the clinical setting and once they have received a CE mark.

[1] http://immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20Public%20Bodies.pdf

[2] The MDR will fully apply from May 2020 for medical devices and the IVDR will fully apply from May 2022

We agree with Ms Moffatt that there is under-reporting of adverse events to MHRA. Our written evidence [3] and our oral evidence on 10 January [4] illustrates the work we are doing to improve this and how this data is considered along with many different data sources to monitor and act fast when a safety concern emerges.

Passage 1 - Exiting the EU and the future of medical device regulation
Whatever the scenario for exiting the EU, we will continue to ensure UK patients are not disadvantaged and can access the best and most innovative medical devices they need quickly.

Passage 3 – Safety and performance of medical devices in humans
It is relatively straightforward to demonstrate the short-term safety and performance of a device which is not intended to be implanted for an extended period of time using a short-term clinical investigation in a relatively small group of patients.

It is not feasible to adequately study the absolute long-term safety and performance of implants in patient groups of enough size and diversity prior to their being placed on the market, which is why the ongoing post-market surveillance of implants is a particularly critical aspect of the regulatory system for these devices. It is the joint responsibility of manufacturers, Notified Bodies[5], clinicians and regulatory authorities to ensure that this happens.

We recognise the need for long-term systematic assessment of the ongoing safety and performance in relation to implants. So, we are supportive of well-designed, sustainable and administered registries.

In addition, the MHRA has been supportive of Beyond Compliance, a programme that has been in place since 2013 to support the introduction of hip and knee implants into use in the NHS. The programme was introduced based on a shared view between clinicians, manufacturers and the MHRA that more needed to be done to ensure that adequate information on the safety and performance of these implants is properly collected and rigorously analysed – particularly in the first few years subsequent to CE certification.

We also welcome the systematic capture of outcome measures (with validated patient reported outcome measures (PROMs) questionnaires as can be seen from the success of the National Joint Registry), as an essential part of a future system that can monitor safety and performance over time, and inform patients, clinicians, commissioners of healthcare, and regulators. All parties concerned can also better understand those patients who have benefitted from these procedures.

Passage 3 - Balance of innovation
The MHRA welcomes innovative medical devices that can bring huge health benefits to people as long as this does not compromise patient safety.

There is a fine balance to be struck between supporting innovation and ensuring appropriate safeguards are in place as ultimately both are in the interests of patients; we should not lose sight of the importance of maintaining proportionate, efficient and effective regulation that will allow us to achieve this.

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[3] http://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20Public%20Bodies.pdf (pdf page 35 and 54)

[4] https://www.youtube.com/watch?v=20BEnbY9L0k&feature=youtu.be (Session 3 MHRA)

[5] independent / third-party certification organisations to assess whether manufacturers and their medical devices meet the requirements set out in legislation

I would like to assure Ms Moffatt and all members of Sling The Mesh and Sling the Mesh Northern Ireland, work continues so that we and all parts of the healthcare system effectively work and come together to understand patient's concerns and to act promptly on information when new evidence about the safety of medical devices emerges.

Thank you once again for the opportunity to respond.

Yours sincerely

John Wilkinson OBE
Director of Devices
MHRA