PE1517/Q

Medicines and Healthcare Products Regulatory Agency Email of 14 August 2014

Dear Andrew,

Thank you for your letter of 5th June. Please accept our apologies for the delay in replying.

MHRA response to Scottish PPPC request to Petition PE1517

What are your views on what the petition seeks and the discussions that took place at the meeting on 3 June?

1. ***Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;***

Any action to remove a device from the market in Scotland would have to be taken by MHRA who have the delegated enforcement authority for the Medical Devices Regulations for the whole of the UK and whose enforcement powers are contained in the Consumer Protection Act 1987. MHRA work to similar principles of risk assessment and proportionality as Scotland and can, as part of their work, also assess the UK situation.

NHS Scotland has its own adverse incident centre for investigating incidents occurring in Scotland. This centre works closely with MHRA and routinely informs MHRA about the occurrence of all incidents and any conclusions reached. This process ensures that MHRA has information on all adverse incidents occurring in the UK, for which it is legally responsible. Thus Scotland is an important contributor and partner in assessing reported post market experience with medical devices.

MHRA assess manufacturer's field safety corrective actions on behalf of the UK and informs Scottish government in advance when it is considering issuing supplementary safety warnings over and above the manufacturer's actions. If this happens Medical Device Alerts are issued by the MHRA for action in England and are sent to the Devolved Governments who have their own contact details within the Alert.

Whether or not a particular medical device is chosen to be used within NHS Scotland is not an issue for UK legislation. It is a decision for NHS Boards, individual clinicians and their patients to consider, taking account of risks and benefits. NHS Scotland is therefore able to advise their institutions and clinicians not to use a particular device if they believe that this is the correct course of action for them.

Any decision or guidance that advises against the use of a medical device on safety grounds would need to be considered carefully with reference to all available evidence, and it would naturally raise questions for MHRA, the other devolved governments, and the rest of Europe.

MHRA sympathise greatly with the women who have experienced very distressing side effects and complications with vaginal mesh implants, and have been actively investigating these devices since March 2011, however the evidence we have to date indicates that a small percentage of the large number of women treated are seriously affected by them. This leads to the conclusion that the benefits of these tapes and meshes currently still outweigh the risks.

We continue to assess and review all evidence available to us which is related to the safety and benefit/risk of these devices. In line with other Regulators worldwide, we have not seen a body of evidence that would indicate that these products should be withdrawn from use.

2. Initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world;

With regard to the request for an Independent Public Inquiry, such decisions need to be proportionate to the need identified, taking into account the likely benefits, time and expense.

MHRA continues to assess and review all evidence available to us which is related to the safety and benefit/risk of these devices and welcome any findings from comprehensive independent research. We strongly advise any women who have experienced adverse effects from these vaginal mesh implants to report them to MHRA.

3. Introduce mandatory reporting of all adverse incidents by health professionals;

Whilst there are regulatory obligations for manufacturers to report and investigate all serious adverse incidents involving their medical devices to the MHRA, it is not compulsory for clinicians to do so.

However, the General Medical Council Guidance published in February 2013 making it clear that clinicians should report medical device incidents to MHRA, and make information available to patients about how they can report side effects to MHRA. ('Good practice in prescribing and managing medicines and devices')

The MHRA also encourages voluntary reporting of adverse incidents by healthcare workers, carers, patients and members of the public

4. Set up a Scottish Transvaginal Mesh implant register with view to linking this up with national and international registers;

The decision about whether a registry is set up will need to be led by the clinical community because any registry must provide outputs that can be used to improve patient care. The MHRA would want to influence the establishment and design of any registry for procedures involving medical devices in order to ensure that the data collected is appropriate for post-market analysis related to the safety of the devices involved. For example, the National Joint Registry is a successful registry that provides valuable information for clinicians and the MHRA about the long-term performance of knee and hip implant procedures.

The British Society for Urogynaecology (BSUG) runs a database for clinicians to enter details about all patients undergoing urogynaecological procedures and NICE guidance for procedures involving mesh advises that clinicians should use this database.

5. Introduce fully Informed Consent with uniformity throughout Scotland's Health Boards; and

Patient consent is not within MHRA's remit, this is best answered by NHS National Services Scotland. We are aware there are consent guidance, consent forms and patient information available from the specialist clinical societies : the British Society of Urogynaecology (BSUG) and the British Association of Urological Surgeons (BAUS).

6. Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.

TVM devices are governed by European Medical Device Regulations. The legislation places obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they are CE marked and placed on the market in any EU member state. Under these regulations vaginal mesh devices are generally classified as Class IIb medical devices which means they are regarded as medium to high risk. These regulations are currently undergoing extensive revision and are expected to require more stringent requirements for clinical evidence for higher risk devices.

There has been little evidence from other European countries of problems or issues with these mesh devices. In March 2014 the European Commission requested a scientific opinion from the European Scientific Committee on Emerging and Newly

Identified Health Risks (SCENIHR) about "The safety of surgical meshes used in urogynecological surgery". This is due to report back in January 2015.

The MHRA is aware of concerns being expressed worldwide with vaginal mesh implants and continues to liaise and exchange information with our counterparts within Europe and worldwide. In line with other Regulators worldwide we have not seen a body of evidence that would indicate that these products should be withdrawn from use.

We are aware of the recently announced proposals by the FDA in the US to reclassify surgical mesh for transvaginal repair of pelvic organ prolapse from a moderate-risk device (class II) to a high-risk device (class III). However the US regulations for medical devices are not the same as the EC regulations, and they cannot be compared. This will be a change for the US, but changing the classification in the EU would have no equivalent effect in Europe and the UK.

I hope you and the Committee find our answers to the points raised in your letter to be helpful. MHRA will continue to work closely with the Scottish Government, including sharing processes for data collection and utilisation across administrations.

Additional information to be aware of, is that MHRA are currently drafting a report summarising available information and evidence on the benefits and risks of vaginal mesh implants, which we intend to feed into both the NHS England led working group on Vaginal tapes and meshes – which includes representatives from the Scottish Government; and the Scottish 'Independent Review of surgery using vaginal mesh' announced by the Scottish Government on 17th June 2014

Yours sincerely

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Medicines and Healthcare Products Regulatory Agency