Department of Health & Social Care

From Jackie Doyle-Price MP
Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention

39 Victoria Street
London
SW1H 0EU

020 7210 4850

Dr Sarah Wollaston MP
Chair of Health and Social Care Committee
House of Commons
London
SW1A 0AA

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Dear Sarah,

Keogh Review of the Regulation of Cosmetic Interventions

Thank you for your correspondence of 24th June to Matt Hancock on the progress of the Keogh Review of the Regulation Cosmetic Interventions.

We want to put in place a national registry of devices. When and how such a registry will be delivered requires further consideration. We remain committed to making improvements to the system of medical device regulation including in response to the Independent Medicines and Medical Devices Safety Review reporting later in 2019.

In addition to a national registry of devices, the Department and the Medicines and Healthcare products Regulatory Agency (MHRA) are leading proactive implementation of planned change at EU level to increase patient safety and confidence in medical devices regulation following the PIP scandal of 2012. The EU regulatory system will be updated through new EU Regulations (2017), which introduce more stringent pre- and post-market requirements for all economic operators within the system.

The new EU Medical Devices Regulations (MDR) and in vitro Diagnostic Medical Devices Regulations (IVDR) came into force in UK law in May 2017 and will fully apply in the EU from May 2020 (MDR) and May 2022 (IVDR).

Before the date of full application, devices that comply with the new Regulations can already be placed on the UK market. These changes to the CE system of assessment include increasing the requirements and scrutiny placed on Notified Bodies; enhancing vigilance and post-market safety surveillance systems; establishing a

higher threshold for clinical evidence before devices can be used in patients; supporting the traceability of devices from manufacturer to end user.

These changes will:

- raise the threshold for clinical evidence required for devices – particularly implants – before they are allowed on the market; ensure CE mark approval is rigorously assessed and not predicated on similar products already approved; and ensure that appropriate post-market clinical follow-up is undertaken;
- significantly increase the requirements and scrutiny of notified bodies and ensure that they are applying the increased requirements for clinical evidence consistently; and
- support traceability of devices through requirements such as Unique Device Identification (UDI) and mandating the provision of implant cards to patients;

The changes will create a new baseline for any further system change we implement after the UK leaves the European Union.

Registered providers must meet the fundamental standards set out in The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Some of the regulations allow direct prosecution when standards are breached. This is set out in CQC's enforcement policy[1] on the website. The steps that a provider should have regard to in meeting the fundamental standards set out in CQC's statutory guidance for providers[2]. This guidance states that 'providers should consult nationally recognised guidance about delivering safe care and treatment and implement this as appropriate'. This would include the Breast and Cosmetic Implant Registry (BRIC) to which all providers of breast implant surgery are expected to participate in.

It is unlikely that the CQC would take steps to cancel the registration of providers should they not comply with this guidance, unless there were additional concerns about the provider's service that were so significant that CQC deemed it posed a serious safety risk to patients. The CQC has confirmed that it could take enforcement action that requires the provider to implement national professional guidance where they are not complying with this and where this poses a safety risk to patients. The CQC could suspend a provider's service in respect of carrying on further breast implant surgery, until it can assure CQC that they are compliant with the guidance. The CQC would also inform the relevant professional regulatory body, such as the GMC and the MHRA.

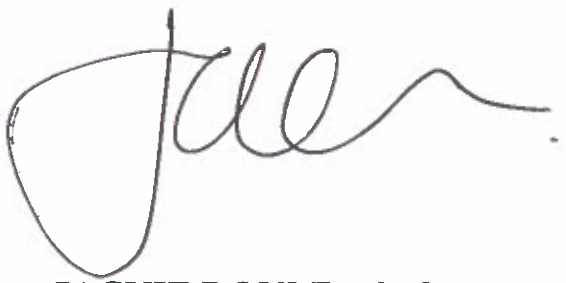
[1] https://www.cqc.org.uk/guidance-providers/regulations-enforcement/enforcement-policy
[2] https://www.cqc.org.uk/guidance-providers/independent-healthcare-services

As set out in the Government's response to the Keogh review, the Government agrees that patients should have recourse to financial compensation if they have been harmed by a practitioner.

All regulated healthcare professionals are required to have in place an indemnity arrangement which provides appropriate cover for their practice. The cover can be an insurance policy, an indemnity arrangement, or a combination of both. The Department has recently consulted on appropriate clinical negligence cover for all regulated healthcare practitioners. The responses are being analysed and a response will be issued in due course.

CQC also assess the financial viability of providers applying for registration under Regulation 13 of the CQC (Registration) Regulations 2009. This states that providers must have "insurance and suitable indemnity arrangements to cover potential liabilities".

As part of the 2017 Conservative manifesto commitment to ensure *"effective registration and regulation of those performing cosmetic interventions"* we are working with key stakeholders from across the industry, including the independent sector, and will continue to explore options to strengthen consumer safeguards, including financial compensation for patients.



JACKIE DOYLE-PRICE