MEETING	**PUBLIC BOARD MEETING** **16 September 2020**
Agenda Item **Paper Number**	**11** **CM/09/20/11**
Agenda Title	**CQC's Response to the Independent Medicines and Medical Devices Safety review (IMMDS)**
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PURPOSE OF PAPER:

- In response to a Board request, this paper providers an update on work on CQC's response to the Independent Medicines and Medical Devices Safety (IMMDS) review, which was Chaired by Baroness Cumberlege.

1. Summary

This paper sets out plans for CQCs proposed response to the recommendations of the IMMDS review and themes from other recent inquiries and reviews[1], as part of the development of the new CQC strategy.

2. Recommendation

It is recommended the board **endorses** work underway to embed CQC's response to the issues and recommendations of the Cumberlege review and other recent external inquiries within the development and implementation of our next Strategy.

[1] Paterson Inquiry report and Gosport War Memorial Hospital; Gosport Independent Panel Report

3. Discussion and implications

The independent medicines and medical devices safety review (IMMDS) was chaired by Baroness Julia Cumberlege and its report, "First do no harm", was published in July 2020. The review was commissioned to investigate what happened in respect of two medications[2] and one medical device[3] and to make recommendations for the future.

Appendix One sets out the review's summary recommendations and the key actions for improvement that specifically reference CQC. We are currently progressing work on CQC's detailed response to the conclusions of the review. The summary recommendations themselves are primarily for other bodies, but there are some valuable suggestions for improvements to our regulatory approach in the review. More generally, there are themes across the review that link to those in other recent external reviews, which it is important that we consider in depth.

The review reflects on a number of key themes, which are also common to the findings of other Inquiries and reviews relating to safety failures in the healthcare system as a whole. This includes the Paterson Inquiry, which was published in February 2020 and examined the malpractice of Ian Paterson a breast surgeon who was convicted of wounding and sentenced to prison in 2017; and the report of the Gosport Independent Panel, which was published in June 2018 and focused on the concerns raised about the care of older patients at Gosport War Memorial Hospital.

Key themes from across the IMMDS, Paterson and Gosport reviews are summarised below:

- **To involve and listen to patients**:

  Often patients were not fully involved in their care, the information they received was limited and the associated risks of the treatment were not clearly explained to them. As a result patients were often left unable to make informed choices about their care. Equally, after treatment when patients, family or friends raised concerns about the care or treatment received, these were often ignored, dismissed or not listened to and individuals were confused by a fragmented and unsatisfactory complaints system. Patient voice and influence in the system needs to be strengthened.

[2] Hormone Pregnancy Tests (HPT) such as 'Primodos' withdrawn from the market in 1970s and which are thought to be associated with birth defects and miscarriages and 'Sodium Valproate' an effective anti-epileptic drug, which causes physical malformations , autism and developmental delay in many children when taken during pregnancy

[3] Pelvic Mesh Implants - used in surgical repair of pelvic organ prolapse and to manage stress urinary incontinence. It's use has been linked to crippling, life changing, complications.

- **An inability to acknowledge when things go wrong and be open and transparent about such failings and learn from mistakes**:

  A consistent theme in this review and that of other inquiries, was a resistance to a no-blame culture within the prevailing healthcare system. Despite the introduction of a number of measures in recent years aimed at encouraging individuals and organisations to be more open and honest when things go wrong there is still too often, a perpetuating culture of denial or unwillingness to speak up based on fear of reprisal or litigation, which prevents learning from mistakes and opportunities to prevent harm at the earliest opportunity. It is apparent that unless we can address the leadership deficit and the cultural attitudes of both individuals and organisations, away from a 'blame culture' to one of learning and a focus on patient safety. We will collectively continue to fail patients and prevent harm at the earliest opportunity.

- **An inability to identify and respond to collective concerns and trends swiftly to prevent future harm:**

  It is recognised that the healthcare system collects a vast amount of data and information but this needs to be used more intelligently to help track patient care pathways longitudinally, used to identify concerns and trends e.g. complaints, monitor and record adverse outcomes, help audit best practice and assist within recalls. However it requires the right data to be collected and as a regulatory body we need to consider how we can make best use of data from incident reporting in a more robust way to help drive improvements in the quality and the safety of the care individuals receive and the medicines and medical devices used.

- **A healthcare and regulatory system which is fragmented and uncoordinated in its responses;**

  Despite the scale of the regulatory system, a common theme across all inquiries was a criticism that it is not joined up, with the individual component parts working in silos to differing standards and directives, which fail to deliver a cohesive approach to patient safety issues. Rather than necessitating more regulation, there is a collective call on the system to become more responsive, joined up and to work more collaboratively to deliver effective regulation on patient safety issues. CQC has a real and significant contribution to make to this agenda going forward.

As is the case with all inquiries with specific CQC recommendations, we are reviewing our inspection methodologies and where appropriate will make changes to our assessment methodology. For example, in response to the Cumberlege Review, work has begun on asking GPs how they respond to patient safety alerts and specific questions in our inspections of GP services in relation to valproate. In response to the Paterson Inquiry, we are beginning work to enhance our assessments of MDT working and our collaboration with other regulators. We will continue to modify our inspection methodologies in response to specific CQC recommendations from these external reviews.

The development of CQC's new strategy for 2021 onwards also affords us the opportunity to take a broader look at our overall regulatory approach in light of the themes identified above. We intend to actively look to build responses to these themes into this strategic work, as well as addressing the more specific recommendation for improvement of individual reviews. This will especially include placing an increased emphasis on the promotion of a 'safety culture' in providers, and developing a shared understanding of what that means and how it applies across the healthcare system.

CQC's current work on the next strategy is based around four themes:

- Meeting people's needs
- Smarter regulation
- Promoting safe care for people
- Driving and supporting improvements

As part of our work under the four themes of the strategy, we will consider how we address the issues from the external reviews highlighted above. While supporting providers to improve safety, we will also need to look at how they are doing it and to share forms of good practice and experience to help drive up improvements across the system as a whole. This is not to stifle innovation and advances in medical care and treatments, but to ensure the healthcare system strikes the right balance between innovation, medical progress and the needs and interests of the patient, and to ensure we create smarter regulation for a safer future.

4. Conclusion and Next Steps

CQC's response to the specific recommendations of the IMMDS review will be published in due course – we do not yet have confirmation of the timing of the Government's response.

Individual lead officers for each of the four themes of the strategy will also be tasked with progressing work to develop our approach to creating a safety culture in the healthcare system; and to actively embed our proposals in each of the four themes of the new CQC strategy. Progress will be reported back to the Board as part of wider work on the Strategy.