General Medical Council

Independent Medicines and Medical Devices Safety Review – response to comments from Sling the Mesh.

1 Thank you for the opportunity to provide further information to the review. In responding to the comments from Sling the Mesh, it may be helpful to first return to our earlier written evidence statement. Within this, we commented on the status and scope of Good Medical Practice (GMP), noting that this sets out the core ethical principles and professional values and standards of competence and conduct expected of all registered doctors. Taken together, GMP and the explanatory guidance that accompanies this, sets normative standards for practice which all registered doctors are expected to follow. And as such, GMP provides the underpinning framework for our system of medical education and training. However, Good Medical Practice is not a statutory code, nor is it a set of rules, and doctors are expected to use their professional judgement on how to apply the principles to the particular situations they face in practice.

2 In all of our guidance we say that 'serious or persistent failure to follow this guidance will put your registration at risk'. Each case turns on its own facts and we will always carefully consider any complaint to ascertain whether the breach of our guidance puts patients or public confidence at risk. If it does we will take action against a doctor's registration to protect patients and public confidence. A serious and persistent failure to comply with any aspect of our guidance, including that relating to the reporting of adverse events, would result in a GMC investigation. However, there is a balance that is needed between supporting an open and learning culture in medicine and taking action against any mistake or failure by a doctor. Requiring the regulator to investigate every error would not support efforts to develop cultures of learning, and would further impede the reporting of incidents and adverse events – a conclusion reached by the Berwick review into patient safety following the tragic events at Mid-Staffordshire NHS Foundation Trust.

3 Effective clinical governance contributes to the safety and quality of patient care. Good clinical governance must support the early identification of risks and concerns that lead to individual, team and wider organisational learning. Last year, along with other key stakeholders, we published joint guidance on *Effective clinical governance for the medical profession* which outlines how robust clinical governance can support doctors to deliver improved quality of care to patients.

4 We firmly believe that our role is best served by investigating and taking action where there are serious and ongoing risks to patient safety or public confidence in doctors. We want to encourage doctors to reflect on and have insight into mistakes or failures and to take action to remediate and improve their practice. A mandatory form of guidance might heighten doctors' fear of the regulator and undermine their own ability to make sound judgements.

5 For this reason, it is our belief that the duty of candour should remain a professional duty rather than a statutory requirement. We believe that it is through strong and effective leadership that organisations will develop a culture in which candour is encouraged and learning from errors is enabled. Where that culture is strong individuals can feel confident about being open when things have gone wrong. The Freedom to Speak Up Guardian Survey, published in November 2018, supports this assertion, identifying an apparent correlation between positive perceptions of speaking up and overall CQC ratings.

6 A mandatory approach would focus attention on the process and whether an event meets a particular threshold of harm, rather than the key principles of openness, honesty and learning that our guidance is seeking to embed. For this reason, our joint guidance with the Nursing and Midwifery Council adopts a dual focus. It encourages learning through the reporting of errors on the one hand while promoting openness, through talking and apologising to patients when things go wrong, on the other. And it is also for this reason that we are increasingly focusing our efforts on influencing the context in which doctor's work to further embed good medical practice.

7 The complaints procedures provide a means through which non-compliance can be addressed, but it is a blunt and less effective instrument for preventing non-compliance in the first place. Effective clinical governance plays a critical role in reducing the likelihood of this by ensuring that care, treatment and support is delivered in line with legislation, standards and evidence-based medicine. Our handbook 'Effective clinical governance for doctors' sets out the core principles underpinning this including the expectation that organisations will put in place processes to support and train staff to report (and learn from) adverse incidents.

8 More broadly, the introduction of the Responsible officer (RO) role provides a more robust level of scrutiny and oversight of doctors. It does so by creating a specific RO responsibility for monitoring the ongoing fitness to practise of doctors connected to them through a system of annual appraisals and a continuous review of clinical governance information including, for example, complaints, outcome data, hospital episode statistics, clinical audit data and incident reports. This facilitates the early identification and resolution of concerns.

9 The introduction of revalidation has been a catalyst for embedding and improving clinical governance systems including appraisal, complaints processes and incident reporting. The revalidation framework and underpinning appraisal systems are structured around Good Medical Practice and its main supporting guidance

documents, including our guidance on the types of information that should be collected to inform the appraisal process.

10 Participation in annual appraisal which includes a review of supporting evidence including patient and colleague feedback, critical incidents, complaints, audit and continuing professional development is a core duty for every doctor. A doctor can lose their licence if they fail to participate in appraisal and engage with the clinical governance systems that underpin it – including the duty to raise concerns and report adverse events.

11 Furthermore, a Responsible Officer will only recommend a doctor for revalidation if they are satisfied that there are no outstanding concerns about their practice. And in making this recommendation they will draw on both the appraisal and wider clinical governance information from each organisation where the doctor works, or has worked, since they last revalidated.

12 In relation to candour, our guidance requires doctors to gather and reflect on complaints, compliments and significant event reviews. It also states that, under the duty of candour, doctors have a responsibility to log incidents and events according to the reporting process within their organisation, and that discussion at appraisal should then include their participation in logging any incidents and events, as well as any learning points that ensue.

13 However, we also believe that appraisal should be a local process and a means for assisting Responsible Officers in determining revalidation recommendations. We therefore do not provide guidance to Responsible Officers or appraisers on probing particular aspects of practice.

14 It is not the appraiser's role to performance manage the doctor and determine whether they have or have not complied with any requirements – they are there to have a formative reflective discussion with the doctor and identify areas for development. If concerns or issues arise then there are processes in place to escalate these to either the lead appraiser or the Responsible Officer directly. It is then up to the RO to utilise other clinical governance processes to look into these issues and take further action if required under their responding to concerns framework.

15 Finally, Sling the Mesh are correct in pointing out that we are unable to identify trends in the reporting of adverse events or to know if doctors are reporting adverse events as and when they occur. We do not require these to be submitted to us (it is the role of the MHRA to collate and analyse this information) and so we do not have any evidential basis for assessing the effectiveness of these reporting arrangements. Our guidance clearly sets out the reporting routes for adverse events, and as noted above, reporting arrangements for both adverse events and patient safety incidents are a component of the clinical governance framework which healthcare providers are required to embed.