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**Chair**  
Professor Terence Stephenson

**Chief Executive and Registrar**  
Charlie Massey

Dear Baroness Cumberlege

## **Re: Independent Medicines and Medical Devices Safety Review**

Thank you for inviting us to contribute to the Independent Medicines and Medical Devices Safety Review and help improve the safety of clinical interventions.

Before responding to your questions, I thought it would be helpful to outline the role of the GMC, and the limits of that role in relation to clinical matters.

The General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK. Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers and patients, to make sure that the trust patients have in their doctors is fully justified.

- We decide which doctors are qualified to work here and we oversee UK medical education and training.
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

We set out the professional values, knowledge, skills and behaviours required of all doctors working in the UK in *Good medical practice* and the associated explanatory guidance. We have a UK-wide remit and our guidance applies to all registered doctors regardless of their specialty, grade and area of work, therefore it is necessarily high level in order to be widely applicable. As it can't cover all of the situations a doctor might face in practice, we expect doctors to use their professional judgment to apply the principles we have in our guidance.

We don't give clinical advice or comment on clinical matters, for example on the safety and appropriateness of interventions or treatments. This is the role of a wide range of other organisations, such as National Institute for Health and Care Excellence (NICE), government health departments and the medical royal colleges. For that reason, we have never published professional guidance on any of the interventions or treatments in scope for this inquiry. However, where our professional standards, or standards for education and training, appear to be relevant I have highlighted them in my responses below

**1. Please could you provide a timeline outlining your understanding and recognition of risks regarding the interventions covered by this Review. This may include: initial recognition of the risk, dates of consequential and significant research studies, and communication of regulatory and professional guidance to clinicians and patients.**

We were invited to participate in a discussion on the use of Sodium Valproate in October 2015 by the MHRA and have been kept updated as part of their wider stakeholder network. As assessment of risk relating to specific interventions or treatments is outside the remit of the GMC, and as other organisations have a more direct role in communicating clinical risks to doctors, we have not published any guidance relating to the interventions covered by this review. We have recently been asked by the MHRA to consider how we might contribute to raising doctors' awareness of the issues around informing women of risks in pregnancy and compliance with the new Pregnancy Prevention Programme, and are discussing with them how we take this forward.

**2. How does the Council ensure that professionals achieve, retain, and update skills relevant to the interventions in question?**

**Medical Education and Training Standards**

Our powers in medical education, as set out in the Medical Act, are two-fold: to set the outcomes for graduates of UK medical schools leading to entry on to the medical register, and to approve the curricula for postgraduate training of doctors. We quality assure both aspects of medical training against our standards set out in [Promoting excellence](#) which was revised and updated in January 2016.

We don't set the content of medical curricula for undergraduate or postgraduate training – and so our standards do not set out the skills required for the specific interventions covered by this review – but I will explain our role in setting standards for medical education in the UK.

*Undergraduate*

Our publication [Outcomes for graduates](#), describes what newly qualified doctors from all UK medical schools must know and do. This will be supplemented by a list of practical procedures – a minimum set of practical skills that newly qualified

doctors must have when they start work for the first time so they can practice safely. The list will be published in spring 2019.

We have no powers to direct the specific content of medical school curricula (undergraduate level), as this is a matter for the 34 individual medical schools across the UK. However, they must demonstrate that they meet both the outcomes and the standards. We make periodic visits to medical schools as part of our quality assurance process to satisfy ourselves that our statutory requirements are met.

### *Postgraduate*

In relation to postgraduate curricula for doctors in training, our recently revised standards, [\*Excellence by design: standards for postgraduate curricula\*](#) describe the GMC's expectations in terms of the process, governance and quality assurance systems required to ensure that the content of curricula reflects the needs of patients, doctors in training and the healthcare systems across the UK. We have requirements that curricula must clearly describe the expected learning outcomes for the area of practice. However, the specific content of each postgraduate specialty curriculum is determined by the relevant medical royal college or faculty. We prospectively review and approve these curricula against our standards.

In terms of learning outcomes, the *Outcomes for provisionally registered doctors* with a licence to practise in foundation year one (F1 doctors) specify what they must demonstrate in order to be eligible to apply for full registration. The *Generic professional capabilities* framework sets out the essential generic capabilities needed for safe, effective and high quality medical care in the UK. *Excellence by design* requires that the generic professional capabilities are included in all postgraduate curricula.

Both these documents, and the *Outcomes for graduates*, set out expectations in relation to doctors' skills in relation to:

- **prescribing medicines safely**, which includes prescribing medications and using other therapies in line with the latest evidence; complying with safety checks and contributing to reporting systems; managing adverse events and reporting adverse drug reactions appropriately
- **using medical devices safely**, which includes complying with safety checks, contributing to reporting systems, and following other appropriate maintenance, monitoring and reporting processes
- **promoting patient safety**, which includes demonstrating that they can participate in and promote activity to improve the quality and safety of patient care and clinical outcomes
- **quality improvement**, which includes improving clinical effectiveness, patient safety and patient experience.

## Medical Licensing Assessment

We are introducing a medical licensing assessment (MLA) in 2022, which all medical students from the UK and doctors from outside the EU will need to sit and pass in order to demonstrate that they meet a common threshold for safe practice before we grant a licence to practise medicine in the UK. The MLA blueprint (content map), which will be published in summer 2019, will be aligned to our other standards and guidance including the Generic professional capabilities framework and the Outcomes for graduates including the list of practical procedures, and underpinned by Good medical practice. The Foundation Programme curriculum is also a key reference document, to ensure consistency as newly qualified doctors enter training.

### **3. If you have had any adverse events concerning the interventions covered by the Review reported directly to the Council please provide an anonymised summary and indicate what actions were are being taken in response to these reports.**

We do not collect reports of adverse events relating to specific interventions or treatments.

### **4. How do you see the Council's role with regard to:**

- a) Adverse events reporting;**
- b) patient safety;**
- c) providing a forum for discussion; and**
- d) potential early warning signal detection?**

As above, the collection and analysis of adverse reports is outside of our remit. However, we do publish professional standards which set out our expectations of doctors in relation to adverse events reporting, which I have set out in my response to question 5.

### **5. Please can you provide details of your relevant policies and protocols, if any, for ensuring that information relevant to patient safety, and learning from adverse events is disseminated amongst your members.**

While we do not have any policies or protocols for disseminating information relating to adverse events, we do publish professional guidance which sets out the responsibilities of doctors in relation to patient safety and adverse event reporting.

In our core guidance, [\*Good medical practice\*](#), we say that doctors must be competent in all aspects of their work and to keep their professional knowledge and skills up to date. That includes being familiar with, and following the law, regulations, guidance and developments that affect their work. They must also take steps to monitor and improve the quality of their work.

In providing clinical care doctors must:

- prescribe drugs or treatment, including repeat prescriptions, only when they have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs
- provide effective treatments based on the best available evidence
- check that the care or treatment they provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications (*Good medical practice*, paragraph 16).

We also say that doctors must take part in systems of quality assurance and quality improvement to promote patient safety (*Good medical practice*, paragraph 22) and contribute to patient safety, for example by:

- contributing to adverse event recognition
- reporting adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk
- reporting suspected adverse drug reactions (*Good medical practice*, paragraph 23).

We expand on these principles in our guidance *Good practice in prescribing and managing medicines and devices* where we say that doctors must make reports in accordance with an employer or contracting body's local clinical governance procedures. Inform the Medicines and Healthcare products Regulatory Agency (MHRA) about: serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the British National Formulary and elsewhere using the Yellow Card Scheme

- adverse incidents involving medical devices, including those caused by human error that put, or have the potential to put, the safety of patients, healthcare professionals or others at risk. These incidents should also be reported to the medical device liaison officer within a doctor's organisation.

In addition, we say that doctors should:

- check that all serious patient safety incidents are reported to the National Reporting and Learning System (in England and Wales), especially if such incidents are not automatically reported through clinical governance arrangements where they work where appropriate, inform the patient's general practitioner, the pharmacy that supplied the medicine, the local controlled drugs accountable officer and the medicines manufacturers of relevant adverse drug reactions and patient safety incidents.

All of our guidance is available on our website, and our liaison and outreach services work with different actors across the UK to improve understanding of our

guidance. [Health system liaison services](#) - Our advisers in England, Northern Ireland, Scotland and Wales work with doctors, patients, medical students and medical educators to promote our standards and improve collaboration and mutual understanding.

[Employer liaison service](#) - Our employer liaison advisers support medical leaders and managers in all sectors, including the NHS and independent providers.

We also offer learning and development opportunities to help doctors understand our ethical guidance and to apply it their day-to-day work. These take the form of workshops for doctors, engagement with students, online learning resources, and further professional learning opportunities. This is in addition to our communication directly with doctors through e-bulletins and various social media about current issues and policies.

## **6. Where within the healthcare system does your responsibility for disseminating adverse event reporting begin and end?**

Our primary responsibilities in relation to adverse event reporting are for the setting of professional standards and overseeing medical education and training, as described above. However we can and do work with other agencies – such as the Medicines and Healthcare products Regulatory Agency – to raise awareness of risks associated with specific medicines and interventions.

## **7. What factors influence the decision on when to update guidance, and how are adverse events reports weighted in this process given the known level of underreporting?**

There are many factors that influence decisions on when to update the professional guidance, including new laws or judicial challenges; examples of poor practice arising from fitness to practise cases; public inquiries or national reports; and enquiries from doctors, patients or others.

As we do not provide clinical guidance, adverse events reports on *individual* interventions or treatments are not significant drivers for the review of the professional standards. However, in response to continuing concern about under-reporting of adverse events more generally we expanded our guidance for doctors on reporting adverse events in the most recent editions of *Good medical practice* and *Good practice in prescribing and managing medicines and devices*.

## **8. What guidance does the Council provide clinicians on informed consent, specifically with reference to communicating risks and complications of intervention (or non-intervention)? Please supply copies of relevant guidance, with the dates during which each version was in circulation.**

Our guidance [Consent: Patients and doctors making decisions together](#) sets out the principles of good decision-making in the context of investigations or treatment

(although the principles also apply more widely). In the guidance we state that doctors should tailor their approach to discussions with patients according to the patient's needs, wishes and priorities. A doctor should also take into account the patient's understanding of their disease, complexity of the treatment and the nature and level of risk associated with the treatment. Doctors must give the patient the information they want or need about:

- a) the diagnosis and prognosis
- b) any uncertainties about the diagnosis or prognosis, including options for further investigations
- c) options for treating or managing the condition, including the option not to treat
- d) the purpose of any proposed investigation or treatment and what it will involve
- e) the potential benefits, risks and burdens, and the likelihood of success, for each option; this should include information, if available, about whether the benefits or risks are affected by which organisation or doctor is chosen to provide care
- f) whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit

In order to have effective discussions with patients about risk, doctors must identify the adverse outcomes that may result from the proposed options. This includes the potential outcome of taking no action. Risks can take a number of forms, but will usually be:

- a) side effects
- b) complications
- c) failure of an intervention to achieve the desired aim.

Any discussion of risk between a patient and doctor must be conveyed in a balanced way. Our guidance states that doctors must explain the expected benefits as well as the potential burdens and proposed risks of harm of any treatment. A doctor must tell a patient if an investigation or treatment might result in a serious adverse event outcome. Doctors should also tell patients about less serious side effects if they frequently.

We are currently reviewing the consent guidance to ensure that it is still clear, accurate, and helpful. At the end of this month we will launch a public consultation to gather feedback from the public and the health and care profession on the new

draft guidance. One of the areas we will be exploring during the consultation is the guidance we give to doctors on communicating with their patients, particularly in relation to explaining benefits and risks of harm.

## **9. How can communication of specific risks to patient groups be improved?**

As outlined in response to question 8, we set out expectations of how doctors should work with patients to understand the risks – including the specific risks material to that patient and what matters to them.

As part of our consent review, we commissioned research with 'seldom heard' patient groups about their experiences of consent and shared decision making, including risk communication. We will send the Inquiry this once published later this month. In essence, it highlighted that in terms of information provision, people tend to be positive towards receiving information in a range of formats, such as graphs and models. They also respond well to the use of real life examples and statistics. Patients are keen for doctors to use terminology that they can easily understand, avoiding medical jargon which can be alienating and intimidating. Participants reported an appreciation for information provision in non-verbal, but engaging or accessible formats such as visual aids, graphs, or models of the human anatomy.

We will be exploring as part of our consent consultation what more can be done to improve communication of risk, particularly in the context of an environment where time and resource are tight.

## **10. Briefly describe your current complaints-handling process. What information is passed on, or otherwise actioned? Is it possible to identify systematically if there are changes in the types and levels of concerns expressed by patients in relation to particular procedures either in the NHS or private practice?**

### **Complaints-handling process**

As part of the GMC's fitness to practise process, we can act on any information we receive from any source as long as it raises a question about a UK registered doctor's impaired fitness to practise. Common sources of information include patient complaints, referrals from employers through responsible officers, self-referrals, media reporting and notifications from the police and other bodies acting in a public capacity.

According to S35C(2) of the Medical Act 1983 (as amended), a doctor's fitness to practise can be impaired by any or all of the following:

- a) misconduct
- b) deficient professional performance

- c) a criminal conviction or caution in the British Isles (or elsewhere for an offence which would be a criminal offence if committed in England or Wales)
- d) physical or mental ill-health
- e) not having the necessary knowledge of English
- f) a determination (decision) by a regulatory body either in the UK or overseas to the effect that fitness to practise as a member of the profession is impaired.

During the course of an investigation, we consider all aspects of a doctor's fitness to practise. In many cases we may consider not only the matters raised in the original complaint, but also any other concerns that have come to light during the investigation. A serious or persistent failure to follow our standards for doctors in Good Medical Practice (and explanatory guidance), which poses a risk to patients or the public or undermines the public's confidence in doctors, will put a doctor's registration at risk.

We are obliged in accordance with our statutory duty to consider all enquiries where there is a realistic prospect of a finding of impairment and as such these enquiries will be referred for further investigation.

However, sometimes it is clear from the outset that an enquiry is not within our remit as it does not raise an issue of impaired fitness to practice, or does not meet our threshold for investigation, and it will generally close with no further action. If the concerns are not within our remit, we will signpost the complainant to the relevant organisation and where appropriate pass concerns on to other regulators.

### **Information Sharing**

On occasion, enquiries will raise concerns which on their own would not raise a question about the doctor's fitness to practise unless they were to be repeated. In these instances the enquiry will close but any learning points raised relating to a doctor's appraisal or revalidation will be referred to the doctor's Responsible Officer or employer. They have responsibility for monitoring their fitness to practise and make recommendations for revalidation. We would also disclose the complaint to the doctor concerned for them to reflect on it. We will only disclose these concerns after first notifying the complainant of how we use their information and considering any concerns or specific requests they share with us about that use, unless it is impracticable or undesirable to do so for public interest reasons.

When considering enquiries we may also come across information which indicates that there are concerns about the systems and environment in which doctors' work and healthcare is delivered. We have a variety of information sharing agreements in place with other organisations and regulators, such as the Care Quality Commission and the police, where we regularly share concerns raised about patient safety. We also regularly correspond with the Department of Health to provide them with details of the investigations we have disclosed to doctors.

We are also responsible for identifying doctors who may pose a risk of serious harm to vulnerable adults and young people in accordance with the Safeguarding Vulnerable Adults Act 2006 and the Protection of Vulnerable Groups (Scotland) Act 2007). Once identified we refer to government agencies who are responsible for protecting vulnerable adults and young people

### **Systematically identifying changes**

In Fitness to Practise, our statutory remit is confined to reviewing allegations of impairment of an individual doctor's practice. Sometimes this might relate to a specific treatment or procedure or it might relate to other procedural or behavioural aspects of a doctor's practice. Therefore the information we gather and record in fitness to practise cases will focus mainly on the categories of impairment for doctors, and not on specific treatments or procedures.

We have an internal review mechanism to enable us to identify information which may indicate significant risks to patient safety or safe medical education and practice and identify any further action we may need to take across the organisation.

We recognise as an organisation we cannot identify concerns alone. We need to work with others to share relevant information about patient safety concerns and trends. For this reason we committed in our Corporate Strategy 2018-2020 to collaborate and share information between regulatory bodies to support safe and high quality care.

To ensure that emerging concerns are dealt with across the healthcare system, we have signed up in July 2018 to the Emerging Concerns Protocol which is coordinated by the Health and Social Care Regulator forum in England. Our devolved offices are also actively involved in national information sharing. In Wales, we sit on the Wales Concordat which meets three times a year to share information, good practice, and discuss ideas to improve regulation, inspection and audit services. In Northern Ireland, we are part of the Joint Regulators Forum and in Scotland, we continue to develop our relationship with the Sharing Intelligence for Health and Care group as part of our commitment to improving the quality of care.

### **11. Of the total numbers of complaints received year on year what proportion relate to:**

- a) Abdominal/vaginally placed mesh procedures;**
- b) sodium valproate and hormone pregnancy tests; and**
- c) informed consent?**

### **How has this changed over time?**

The information we hold in our complaints relates to allegations of impairment of doctors. As the abdominal/vaginally placed mesh procedures and sodium valproate

and hormone pregnancy tests relate to specific medical treatment and devices and not the categories of impairment for doctors, we don't routinely collect information in a way that easily enables an analysis at this level of detail. However, we would be open to a further discussion with you as to the information we may be able to provide related to this, if that would be of benefit to you.

We do hold information related to allegations of lack of informed consent as this relates to a doctor's knowledge and practice. The information below includes the total number of enquiries we have received which refer to a lack of informed consent. This would include where the doctor has either not obtained adequate informed consent from a patient before carrying out an examination /investigation or where the doctor has inappropriately used the patient's medical records or private information in research without consent:

- In 2016 we received 130 enquiries
- In 2017 we received 254 enquiries
- So far in 2018 we have received 175 enquiries.

## **12. How do you feel the culture of reporting concerns and adverse events by clinicians and others within the healthcare system has changed? What barriers, if any, do you feel inhibit open disclosure and reporting? What, if anything, could be done to improve this?**

We understand that speaking up can be a daunting prospect for doctors and that we have a role to play, alongside others in the healthcare sector, in helping to develop a culture in which openness and honesty is the norm, ensuring that concerns are shared at an early stage and acted on as soon as possible.

As well as organisational duties, there is an individual professional responsibility on all doctors to raise and act on concerns. Our guidance [Raising and acting on concerns about patient safety](#) sets out managers' responsibilities to ensure there are systems in place to allow concerns to be raised and investigated and that staff who raise concerns are protected from unfair criticism or action.

Our confidential helpline (established in 2012) gives doctors across all four countries of the UK a means to raise serious concerns with us. Since 2014 we have received over 200 calls to the helpline from across the UK, the majority of which have led to further investigation. Via our liaison advisers, we proactively raise the profile of this guidance especially with doctors new to UK practice and doctors in training. In England we are working closely with Freedom to Speak Up Guardians whose role is to lead culture change within NHS organisations so that speaking up becomes business as usual. As part of our broader Supporting a Profession Under Pressure (SAPUP) work, we are developing web theme content to support doctors raise and act on concerns.

In August of this year, we, along with seven other regulators, launched the Emerging Concerns Protocol. The Emerging Concerns Protocol strengthens existing arrangements, providing a clear mechanism for organisations to raise concerns and arrange meetings where they can be discussed. This collaborative approach will help us better identify emerging risks, so they can be addressed in the fastest, most effective and coordinated way possible

**13. How do we ensure that clinicians respond appropriately to patient concerns?**

*Good medical practice* states that all doctors have a duty to listen to patients, take account of their views, and respond honestly to their questions. When a doctor is on duty, they must be readily accessible to patients and colleagues seeking information, advice or support.

As a regulator we are responsible for setting and implementing the standards expected of doctors and for supporting registrants to understand and apply these standards in practice. We aim to do this through the production of online learning materials, delivering sessions to doctors on effective communication, raising concerns and duty of candour, and emphasising the importance of candour throughout each stage of a doctor's career.

**14. What would you consider to be the defining features of an effective clinical registry? Who is best placed to host such a registry? How can healthcare professionals be encouraged to use the registry?**

This is not a matter we are well placed to comment on.

**15. Could you please outline the role of the GMC in compiling the British Pharmacopoeia from 1950 to 1971? We are particularly interested in any information regarding Hormonal Pregnancy Tests during this period.**

From 1928 to 1968 the GMC, along with Medical Research Council and three pharmaceutical societies, formed a selection committee to appoint the Pharmacopoeia Commission who were responsible for compiling the British Pharmacopoeia. Between 1950 and 1968, the British Pharmacopoeia was published 3 times. To further ascertain if we had any role beyond appointing the Commission, or if we held any information regarding Hormonal Pregnancy Tests during this time, we will need to access off-site records.

Thank you for the chance to engage with this review. I hope you find these responses useful. If any clarification is sought or there are any further questions, please contact us.

Yours sincerely