Authority response to *First Do No Harm*, the report of the Independent Medicines and Medical Devices Safety Review (the Cumberlege Report)

September 2020

1. Key points of the Authority's response to the report

1.1. The Professional Standards Authority for Health and Social Care (the Authority) notes the recent publication of *First Do No Harm - The report of the Independent Medicines and Medical Devices Safety Review* ('the Cumberlege Report') and its recommendations for regulation of medicines and medical devices and the regulatory system overall.

1.2. **We acknowledge the huge damage caused to patients by the medicines and medical devices examined within this review as well as the finding by this and other reviews that patients' voices have not been heard**. We fully agree that the system must change to prevent this happening again.

1.3. **We support the recommendation to create a Patient Safety Commissioner to promote and improve patient safety and represent patients' interests.** Due to the complexities identified across the system in relation to different bodies with differing but overlapping responsibilities, Government should consider broadening the remit for this role beyond medicines and medical devices. This would allow the Patient Safety Commissioner to act as a 'navigator of the system' and a means of amplifying the patient voice across health and care. It is essential that the Commissioner has the independence, standing and resources necessary to make the role effective.

1.4. **We recognise the concerns raised by conflicts of interest in the report, and we agree that interests need to be declared.** However, in relation to the proposal for the General Medical Council (GMC) to indicate doctors' financial and non-pecuniary interests on the medical register, while we share the objective of transparency, we caution about providing information in this way and suggest there may be alternative ways to achieve the outcome sought. This could include more effective enforcement of existing measures for manging conflicts; providing information locally, for example on employer or registrant websites; and for regulators to ensure that any breach of the relevant standards is addressed through their existing complaints process. It will be important to listen to the views of patients' organisations before deciding what the most appropriate options are.

1.5. **We will support work by the GMC and the other professional regulators in considering what further action can be taken and in seeking to ensure a consistent approach.** We will ensure the findings from the Cumberlege review are reflected in our regular published reviews of the regulators and are taken into account in our planned review of the performance review process.

1.6. **We note that this review identified gaps in the regulatory system and the risk of patient safety concerns falling between different bodies.** This mirrors the recent findings from the Paterson Report published earlier this year which highlighted the fragmented nature of the regulatory landscape; and echoes similar findings by the Francis Inquiry in earlier years.

1.7. **Government should take account of the findings from these and other recent inquiries when shaping the Medicines and Medical Devices Bill** currently going through Parliament and other areas of Government policy such as the planned reforms to professional regulation and ensure that any legislative change supports moves towards a more coherent system.

2. First Do No Harm – The Independent Medicines and Medical Devices Safety Review (the Cumberlege Report)

2.1 We welcome the publication of the Cumberlege Report. We do not have specific comments on the findings and recommendations on the regulation of medicines and medical devices. However, we comment below on those relevant to professional regulation and to the regulatory system as a whole.

Gaps in the regulatory system and proposals for a Patient Safety Commissioner

2.2 We note the finding of the report regarding the failure of the regulatory system as a whole and that the linkages between different bodies and the oversight of the system overall had not worked. This finding mirrors the findings from the Paterson Inquiry that there is a 'jigsaw of organisations' to keep patients safe and yet failures still occurred. We acknowledge the huge damage caused to patients by the medicines and medical devices examined within this review and fully agree that the system must change to prevent this happening again.

2.3 We support the recommendation to create a Patient Safety Commissioner to promote and improve patient safety and promote and represent patients' interests in relation to the regulation of medicines and medical devices. Sadly, a number of inquiries have concluded that patients' voices have not been heard or heeded within health and care generally, and so we agree that they need a champion and a means of amplifying the patient voice across health and care. However, Government should consider carefully the purpose of this role and whether the remit is broadened beyond medicines and medical devices and can therefore act as a 'navigator of the system'.

2.4 In *Rethinking regulation* we said '…It is harder still to keep track of the total number of organisations involved in the regulation, inspection, audit and scrutiny of different aspects of health and social care services, from medical devices to health and safety in residential homes. This structure makes it impossible for members of the public to navigate their way through. The organisations themselves must divert their resources into attempting to manage numerous jurisdictional boundaries and attempts to work collaboratively become cumbersome and bureaucratic'.[1]

[1] Professional Standards Authority (2015) *Rethinking regulation*.

2.5 In our view the Patient Commissioner role will not help if it is just another player in this complex landscape. It will need to be a role which helps patients navigate these complexities, and which helps organisations to work in a coherent way across jurisdictional boundaries in the interest of patients. It is also essential that the Commissioner has the independence, standing and resources necessary to make the role effective.

2.6 We note the comparisons in the report to the oversight role the Authority provides for professional regulation. As part of the reform of professional regulation we have asked Government to review how the Authority's role is intended to contribute to wider patient safety objectives, particularly in light of the findings from the Paterson Inquiry that the Authority 'lacks the mandate or powers to fully grip the system'.

It is important that the changes currently proposed for professional regulation don't leave the Authority less equipped to carry out its role effectively.

Conflicts of interest

2.7 We note the recommendation for the GMC to include on the medical register the financial and non-pecuniary interests for all doctors, as well as doctors' clinical interests and specialisms; for other regulators to consider similar requirements as necessary; and for the Authority to evaluate whether conflicts of interests have been adequately declared.

2.8 We recognise the concerns raised by conflicts of interest in the report, and we agree that interests need to be declared. However, it is important to ensure that information provided on professional registers is not misleading and we suggest that there may be alternative solutions to this problem which may be more helpful to patients. We suggest that more effective implementation of existing measures for managing conflicts may be a better way to achieve the outcome sought.

2.9 In *Good Medical Practice* the code of practice for doctors the GMC states: 'If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making'.[2] We would expect the GMC to ensure that guidance on this for registrants is up to date and to actively monitor this and take action on concerns raised about registrants.

2.10 As part of the performance review, under the Authority's Standards of Good Regulation, Standard 6 (maintaining up to date standards for registrants) we would be able to explore this and would ask specific questions about the GMC's handling of this through a targeted review.

2.11 With regard to the proposal for the GMC to include further information on interests on the register, it is important to understand that registers are more than a list. They provide assurance that registrants have met certain standards – they are not just a repository of information. There is a risk therefore that the public may assume that all the information has been validated by the GMC and

[2] General Medical Council, *Good Medical Practice*, paragraph 79 *Honesty in financial dealings*. Available at: www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice

that no conflict exists. We think this could be administratively complex and burdensome to implement, and potentially misleading. We also know from our consumer research that the public have low awareness of regulators and do not routinely check registers.

2.12 We suggest instead that displaying such information at a local level, for example on the registrant or employer website where patients are more likely to be able to access it may be more effective. The GMC then has a duty as a regulator to ensure that its registrants do declare such conflicts in line with the code of practice and to take action against any failure to do so. It will however be important to listen to the views of patients' organisations before deciding what the most appropriate options are.

2.13 We will support work by the GMC and the other professional regulators in considering what further action in this area is required and to promote a consistent approach. In relation to our own role in this area, we are about to begin a review of the performance review process and will ensure this recommendation is taken into account in this process.

Duty of candour

2.14 We note the observation in the Cumberlege review that the duty of candour has not been entirely effective and the reference to the Authority finding in our 2019 report that the regulators are not always identifying duty of candour breaches or considering them as part of fitness to practise hearings.

2.15 We have carried out work to identify the barriers to candour and made recommendations to embed the professional duty of candour.[3] Many of these relate to creating a culture of candour and addressing barriers within workplaces, however we have also suggested the need for greater clarity of how it should be applied across the four countries of the UK[4] and between the statutory and professional duty of candour.

2.16 We have previously suggested a common candour standard across the professional regulators would help to highlight its importance and embed a shared understanding amongst healthcare professionals. However, it is also important to gain a better understanding of the barriers to candour, including psychological barriers in order to support actions to create open, supportive workplace cultures where candour is encouraged.

[3] The Duty of Candour. Available at: www.professionalstandards.org.uk/what-we-do/improving-regulation/find-research/duty-of-candour

[4] Primary legislation setting out an organisational duty of candour in the NHS in Wales was passed in March this year. Further regulations are required for the duty to be implemented. Northern Ireland is reviewing the legislative requirements following the recommendation from the Hyponatraemia-Related deaths Inquiry that a statutory duty of candour be introduced.