Dear colleague,

I am writing in response to the Department of Health and Social Care's consultation on changes to the Human Medicines Regulations. I appreciate the Department's willingness to listen to feedback received after the consultation formally closes and hope this forms part of an ongoing dialogue as decisions are made.

In summary, we welcome the rapid roll-out of a safe and effective vaccine and treatments for COVID-19 and are keen to understand how the proposals will be accompanied by appropriate safeguards. Doctors and other healthcare professionals will play a critical role in the delivery of a vaccine, and it is important they are appropriately supported.

We have commented on specific parts of the proposals below. We recognise that some of our comments relate to issues that the Department is not specifically consulting on at this stage. However, we would like to set these out so that the Department can consider them as part of the ongoing planning for COVID-19 vaccines, and the implementation of the proposed changes for other medicines in the future.

Our role

The General Medical Council (GMC) is an independent organisation that helps to protect patients and improve medical education and practice across the UK.

• 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.

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.

Key issues

Temporary authorisation of the supply of unlicensed products and clinical guidance

We agree that supplying unlicensed products, including COVID-19 vaccines, should be subject to conditions such as sufficient evidence of safety, quality and efficacy. In our ethical guidance we say that, when prescribing an unlicensed medicine, doctors must be satisfied there is sufficient evidence of using that medicine to demonstrate its safety and efficacy (please see paragraph 70, *Good practice in prescribing and managing medicines and devices*).

Prescribers will also need clear and timely authoritative clinical guidance to support the safe prescribing of medicines with temporary authorisation issued to protect the public. It is not the role of the GMC to provide clinical guidance and it is therefore important those with relevant expertise ensure health professionals are able to access the required clinical guidance and advice. We will work with relevant bodies to signpost and promote relevant

guidance to ensure doctors are able to apply their professional judgement within an appropriate framework.

Communicating the risks and benefits of the vaccine

We understand that, under the Regulations, the MHRA may consider if the balance of risk and benefit to patients justifies the temporary supply of a relevant vaccine (in this case, for COVID-19) pending the issue of a product license. We recognise the need for the rapid roll-out of a safe and effective vaccine and the critical importance of ensuring a sufficient level of uptake to protect lives. In doing so it is important to ensure that the risks and benefits to the public are communicated clearly and transparently. This will be important at both the national level and between doctors and individual patients. We would expect any doctor offering an unlicensed vaccine to ensure that they have informed consent before providing the vaccine to patients (see paragraph 17 in *Good medical practice* and our guidance on *Decision making and consent*).

Clear, accurate information about the risks of any proposed treatment, presented in ways patients can understand, can help them to make informed decisions. Discussions with individual patients should focus on their specific decision and the risk to them as set out in our guidance on consent. If treatment might result in a serious adverse outcome, we expect doctors to tell patients, even if the likelihood is very small. Information about risks must be provided in a balanced way. It is important to avoid bias and explain expected benefits as well as any potential burdens and risks of treatment. These discussions will also need to be informed by appropriate clinical guidance, as mentioned previously.

Ensuring that the risks and benefits of a new vaccine are clearly communicated will also support the public's understanding of a vaccine, build trust and tackle misinformation.

Civil liability and immunity

We understand the Department proposes extending existing immunity under the Regulations, currently possessed by manufacturers and healthcare professionals, to pharmaceutical companies. We understand that the Department believes that serious breaches of conditions set by the MHRA's approval should lead to a loss of immunity from civil liability. As part of the Department's communication of its policy in this area, we believe it will helpful to clarify the respective roles of civil liability, criminal liability and regulatory action, as well as when immunity does, and does not, apply to doctors and other healthcare professionals

Proposed expansion to the workforce eligible to administer vaccinations

To ensure the workforce is available to administer vaccines in a timely way, the Department may wish to consider a potential role for Medical Associate Professions (MAPs) to support this. While Section 18 powers remain in place, there is also scope to draw on the resource of doctors who remain on our temporary register.

The consultation also includes proposals to extend the role of administering vaccines to registered healthcare professionals who do not normally vaccinate, and to people who are not registered healthcare professionals. Ensuring that an expanded workforce has the required competence, skills and knowledge to safely administer the vaccine is vital.

We understand that, in advising the Government on which COVID-19 vaccine(s) to use, the Joint Committee on Vaccination and Immunisation (JCVI) will consider those who are most

at need (including health and care workers). It is important that doctors and other healthcare professionals are considered as a priority group for vaccination. We would also encourage the JCVI to consider the needs of BAME and other groups which may be at greater risk.

Provisions for wholesale dealing of vaccines

The consultation includes proposals designed to allow a vaccine to be rapidly distributed across the UK. This could involve waiving the need for a wholesale dealer's licence to facilitate the rapid transfer of COVID-19 and flu vaccines, and other medicines for treatment in response to a public health crisis.

The consultation acknowledges that further guidance would need to be specified in this area. While this issue does not fall within our remit, we believe that it is important that relaxing the need for a wholesaler dealer's licence does not create risks to patient safety. This includes ensuring that vaccines and other medicines are securely and safely stored and transferred to patients in need. Appropriate safeguards need to be put in place to safeguard against medicines being administered to the wrong patients or diverted into criminal use. The DHSC may wish to consider if more can be done to ensure suitable premises are made available in a timely way to support a secure supply chain without the need to waive a licence.

Broad scope of changes and potential for unforeseen future implications

The proposed changes apply beyond COVID-19 more widely to immediate risks to public health. There is potential for unforeseen implications as the proposals could be applied to potentially dangerous medicines in the future.

We therefore believe it is important that the Department ensures that plans to relax existing requirements are temporary and subject to review, to ensure patient safety. We understand that some of the provisions in the proposed draft regulations are time-limited or have review provisions built into them. It would be helpful if the Department clearly set out why some measures have been subject to this, but not others.

We believe that it would also be beneficial to develop a framework for the evaluation of the Department's proposals. This could evaluate the risks/adverse impacts and the benefits, drawing on patients', healthcare professionals' and other stakeholders' experiences of the proposed changes. Ultimately, this evaluation framework could generate learning that could ensure patient safety in the authorised use of unlicensed medicines under the Regulations in the future.