

## GMC response MHRA consultation on EAMS

September 2021

- 1 The 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.

We welcome the opportunity to respond to the MHRA's consultation on proposed legislative changes, which aim to clarify the legal basis of the UK Early Access to Medicines Scheme (EAMS). We have restricted our comments to a specific area that is relevant to our guidance for doctors on professional standards.

The consultation explains that the proposed legislative provision aims to provide clarity around the use of medicines during the EAMS. It states that the provision will align with our guidance for doctors on prescribing unlicensed medicines and licensed medicines 'off-label'.

We understand that the provision's scope will be specifically limited to the prescribing of these types of medicines within the EAMS. We think it is important to avoid any unintended consequences of legislative changes creating new legal requirements regarding the prescribing of unlicensed and off-label medicines more generally (i.e. outside the EAMS). Wider changes would require appropriate engagement and consultation with relevant stakeholders. We appreciate this is not your intention, so it would be helpful to ensure the scope is made clear throughout.

We note that the section of the consultation that refers to our guidance for doctors is titled: 'Clarifying the liability for prescribers and patients'. We are unsure whether liability in this context refers to legal liability (for instance, in the event that a patient suffers harm after being prescribed a medicine). However, it may be helpful to clarify that our guidance sets out standards of good practice, it does not address the issue of legal liability.

We would be pleased to discuss these issues further with you and your colleagues, if helpful.