Access to new medicines – Call for written views

Thank you for the opportunity to submit our written views on the effectiveness of the changes to the system for approving new medicines. Whilst we will not comment directly on these changes, this response outlines the General Medical Council’s (GMC) position with regard to new medicines. To give some context to this reply I would like to outline the role of the GMC.

Our role

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.

Our team in Scotland helps the GMC to fulfil its statutory role as a UK wide regulator and ensure that Scotland’s voice is heard across the organisation. The team represents the GMC, engages key interests in our work and leads our public affairs and professionalism work in Scotland.
Setting the standards for doctors

Our standards define what makes a good doctor by setting out the professional values, knowledge, skills and behaviours required of all doctors working in the UK. We consult with a wide range of people, including patients, doctors, employers and educators to develop our standards and guidance.

The core professional standards expected of all doctors are set out in *Good medical practice* which covers fundamental aspects of a doctor’s role, including working in partnership with patients and treating them with respect. We provide detailed guidance on ethical principles that most doctors will use every day, such as consent and confidentiality, and specific guidance on a range of areas such as raising concerns about patient safety, doctors’ child protection responsibilities, and providing care for people who are dying. We also develop case scenarios and tools that help doctors apply the principles in their practice.

Our professional standards are all consistent with and reflect the laws of the four countries of the United Kingdom.

Serious or persistent failure to follow our guidance will put a doctor’s registration at risk.

New medicines

The following paragraphs outline some the GMCs guidance to doctors with regard to prescribing, and its stance regarding unlicensed medicines:

1. In paragraph 11b of our [prescribing guidance](#) we say doctors should take account of the clinical guidelines published by the Scottish Medicines Consortium and Healthcare Improvement Scotland (including the Scottish Intercollegiate Guidelines Network).

2. Our prescribing guidance outlines consent issues as they pertain to prescribing of any medicine. Specifically:

   2.1 Paragraph 23 outlines that doctors should identify the likely cause of the patient’s condition and which treatments are likely to be of overall benefit to them.

   2.2 Paragraph 24 outlines that doctors should reach agreement with the patient on the treatment.

   2.3 Paragraph 25 outlines that the amount of information doctors give to each patient will vary according to the nature of their condition, the potential risks and side effects and the patient’s needs and wishes. Doctors should check with patients that they have understood the information, and encourage them to ask questions to clarify any concerns or uncertainty.
Unlicensed medicines

3 In our prescribing guidance we use the term ‘unlicensed medicine’ to describe medicines that are used outside the terms of their UK licence or which have no licence in the UK. We use this term rather than a combination of ‘unlicensed’ and ‘off label’ because the ethical issues we expect doctors to consider and the actions we expect them to take are the same for both – considering the individual patient’s clinical need, being satisfied by the available evidence, and making decisions in partnership with patients. We also alert doctors to the advice from the Medicines and Healthcare Regulatory Agency on the use of medicines outside the terms of their license. In November, we issued a ‘hot topic’ to all doctors on these issues which is available at http://www.gmc-uk.org/guidance/28349.asp.

4 In paragraph 68 of the guidance we say that doctors should usually prescribe licensed medicines in accordance with the terms of their licence. However, we also say that doctors may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient. This should be done with the patient’s, or guardian’s, fully informed knowledge and consent (see paragraphs 21-29).

5 We believe that our guidance in relation to unlicensed medicines is in line with the European licensing laws. We appreciate the important role that such laws play in public protection and recognise that careful consideration needs to be given before such laws can be set aside in order to cut costs. The GMC cannot issue guidance that is unlawful.

6 As an example, in 2015 we received a lot of correspondence in relation to prescribing Avastin for chronic eye conditions, a use which is outside of the terms of the UK licence and therefore unlicensed in the context of our guidance. We have given this matter much thought, and understand and sympathise with the difficult situation. As well as responding to all correspondence, our Chair Professor Terence Stephenson has also written to the Secretary of State in England to clarify the current position. Having received a response from George Freemen, MP, and having had many conversations with organisations such as the MHRA, we have been assured that our current position is correct.

7 Our guidance was published in 2013 and we do not have any immediate plans to review the guidance as we believe that it is still relevant and legally sound. We normally aim to review our guidance every five years unless there is a significant change in the legal or clinical landscape in which case we may consider bringing the review forward. We do not believe that the legal position in relation to prescribing unlicensed medicines on cost grounds has changed since the guidance was published.
We will of course continue to monitor the legal landscape and engage with our colleagues on the matter.

We fully recognise the importance of ensuring patient safety through a strong licensing regime, whilst also enabling patients to get access to new drugs in a timely way where there is strong evidence of effectiveness and safety. We know the issues are complex and that other parts of the UK are also looking at possible options. If there is more we can do to be involved in finding a way forward, we would be happy to do so. If you would like to explore this further, or if you have any further questions, please do get in touch.

Yours sincerely

Victoria Carson
Head of Scottish Affairs
Email: vcarson@gmc-uk.org
Telephone: 0131 525 8706