Dear Sir/Madam

Pregabalin and gabapentin: proposal to schedule under the Misuse of Drugs Regulations 2001

The British Medical Association (BMA) is a voluntary professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care.

We wrote to the Home Office in August 2017 to raise concerns that our members have highlighted about the problems of abuse and addiction to pregabalin. We welcome the opportunity to respond to this consultation on proposals to make pregabalin and gabapentin controlled drugs. Our responses to the consultation questions are set out below.

In light of the risks of diversion from legitimate uses and the harms identified in the ACMD (Advisory Council for the Misuse of Drugs) advice, which option do you support? Please explain why:

Of the 3 options that the consultation outlines, we support option 2 – to place pregabalin and gabapentin in Schedule 3 to the 2001 Regulations, but excluding application of safe custody requirements.

Pregabalin and gabapentin are widely used in the UK for the treatment of neuropathic pain and refractory epilepsy. Pregabalin is also licensed in the UK for the treatment of generalised anxiety disorder. There has been a steep rise in the rate of prescribing over recent years. In 2016, 5.5 million items of pregabalin and 6.4 million items of gabapentin were prescribed in primary care in England alone, an increase of 152% and 120% respectively since 2011.

Although pregabalin and gabapentin are an important treatment option for many patients, they are also associated with problems of abuse and addiction. They can, when misused, produce a similar euphoric high to opiates and when used along with opiates, they can enhance the high and in overdose can cause drowsiness, sedation, respiratory failure and death. Our members have raised particular concerns about their impact in prisons, where when misused they are associated with addiction, trading, overdose and bullying, both on the wings and in consultation rooms. We also have concerns about the pressure put on clinicians in out of hours and urgent care services for repeat prescriptions.
Given these harms but recognising their legitimate uses, we believe it is important that pregabalin and gabapentin be made a controlled drug, in a similar way that tramadol was in 2014 (Schedule 3, with no safe custody requirements). In August 2017 we wrote to the Home Office, broadly supporting the ACMD’s 2016 recommendation to control pregabalin as a Class C, Schedule 3 substance.

We do not believe that the Government should take option 1 – full Schedule 3 status under the 2001 regulation, requiring safe custody arrangements. As we have noted, pregabalin and gabapentin have important uses and are widely prescribed. As a consequence of the number of prescriptions that are dispensed, our members have raised concerns that existing safe storage facilities in many dispensing practices would be inadequate, particularly in small rural practices. Should premises be unable to store sufficient quantities on site, then this may lead to shortages and leave patients having to face rapid withdrawal. We do not believe that option 3 would provide the necessary safeguards against the misuse of pregabalin and gabapentin.

Do you agree with the impact assessment of option 1?

We agree with the benefits outlined in the impact assessment. Our members are concerned about the association of pregabalin and gabapentin with addiction, trading and misuse, particularly in prisons. The proposed scheduling arrangements would ensure greater controls on prescribing and better safeguards against diversion. This has been shown to be effective for other controlled drugs such as tramadol. We agree with the impact assessment about the likely savings for the health service and the reduced harm to individuals by making diversion more difficult.

The impact assessment assumes that there will be costs to businesses from option 1, but does not expect that there will be public sector costs as these will be subsumed into the enforcement and regulatory responses to other controlled drugs. We disagree with this assessment. We believe that the scale of prescribing of pregabalin and gabapentin will mean that existing safe storage facilities, may in some cases have to be expanded. This will mean additional cost and may be impractical where space is a premium. We note that the assessment acknowledges that a mandatory requisition form will need to be completed each time dispensing GPs obtain stock for use in the community. While we recognise that this is necessary, this will create an additional burden for GPs who are already under pressure.

Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of controlled drug licensing requirements or associated with prescription forms, as a result of option 1?

We believe that classifying pregabalin and gabapentin as a schedule 3 controlled drug, would also be an important step in protecting healthcare workers from abuse. The concerns our members have shared about trading and bullying associated with pregabalin and gabapentin extends from prison wings to consultation rooms. The BMA has long been concerned about the risk and impact of violence on NHS staff and is particularly worried by the rising numbers of attacks taking place against frontline staff. Latest figures reveal that the total number of assaults on NHS staff in the year to the 31st March 2016 was 70,555 up from 59,744 in 2011/12. We believe that option 1 would help to tackle the specific problems with bullying and violence towards staff associated with pregabalin and gabapentin.

To help inform the full impact assessment please quantify the additional cash cost per month of this proposal to you or other organisations

We do not have detail about the additional cost of option 1 to GP dispensing practices and secure environments. However, as we have highlighted, we would expect that some practices will incur additional
cash costs to set up safe storage facilities large enough to accommodate the volume of pregabalin and gabapentin that is required.

Do you agree that healthcare organisations or businesses will be able to accommodate pregabalin and gabapentin within current compliant safes?

No – we are concerned that existing compliant safes or medicines cupboards will be inadequate for the volume of medications needed in some GP dispensing practices, for example rural premises. A compliant safe storage facility could be purchased at the cost of several hundred pounds per practice, but in some cases it may not be possible to install a new facility where there is inadequate space. This may result in short-term shortages, which could leave patients having to deal with rapid withdrawal symptoms.

Do you agree with the impact assessment of option 2?

We agree with the conclusions in the impact assessment about the costs to businesses and the public sector. The assessment does not make a comparison to the other options. We believe that option 2 would mean GP dispensing practices and prison health services would incur less cost than option 1, by removing the safe custody requirements.

We also support the conclusions in the impact assessment about the benefits of option 2. We agree that it would introduce proportionate controls on pregabalin and gabapentin, which would have a similar effect to option 1. In the absence of robust evidence of diversion from healthcare facilities, we believe that option 2 is more proportionate, as it would provide the necessary safeguards and allow the continued prescribing of pregabalin and gabapentin for the legitimate treatment of chronic pain without creating significant additional cost. We do not believe there is evidence to support making pregabalin and gabapentin more tightly controlled than other Schedule 3 drugs such as tramadol.

Are you aware of any other impact on healthcare professionals, institutions, or industry, including those resulting from application of controlled drug licensing requirements, or costs associated with prescription forms, as a result of option 2?

We would anticipate that option 2 would provide similar safeguards to option 1 in terms of reducing the abuse of healthcare workers. Controlling pregabalin and gabapentin would reduce the likelihood of trading and bullying by more closely monitoring prescribing. We are not aware of any other impacts that are not also included in the assessment.

To help inform the full impact assessment please quantify the additional cash cost per month of option 2 to you or your organisation.

We do not know the specific additional cost of option 2, but would anticipate that it would be lower than option 1, as a consequence of not having to install large and costly safe storage facilities.

Do you agree with the impact assessment of option 3?

We agree that option 3 would lead to less cost than options 1 and 2, as a consequence of not applying safe custody and prescription requirements. We do not believe that this option would effectively tackle the harms associated with pregabalin and gabapentin. We therefore support the conclusion in the impact assessment that there may be associated costs for the health service of having to deal with these harms downstream. We also agree with the assessment that option 3 would produce limited benefits compared to the other options.
Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of controlled drug licensing requirements, or costs associated with prescription forms, as a result of option 3?

We do not believe option 3 will be as effective at tackling the diversion and misuse of pregabalin and gabapentin. We therefore have strong concerns that it may not provide the necessary protections from bullying and abuse, which healthcare professionals need.

To help inform the full impact assessment please quantify the additional cash cost per month of option 3 to you or your organisation.

We do not know the specific additional cost of option 3, but would anticipate that it would be lower than option 1, as a consequence of not having to install large and costly safe storage facilities.

In your (or your organisation’s) view how much lead time is necessary for implementation if option 1 was adopted?

We believe 6 months may be necessary to allow dispensing GPs and pharmacists to create the required space and install new safe storage facilities.

In your (or your organisation’s) view how much lead time is necessary for implementation if option 2 was adopted?

We believe 3 months would be necessary to implement option 2, in order to raise awareness of the new requirements and ensure processes are put in place.

In your (or your organisation’s) view how much lead time is necessary for implementation if option 3 was adopted?

We believe 3 months would be necessary to implement option 3, in order to raise awareness of the new requirements and ensure processes are put in place.

We hope that our submission is useful – please do not hesitate to contact us for more information if required.

Yours sincerely

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