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

Who we are
The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom. With over 17,000 members, our primary aim is to represent, support and champion the interests of the United Kingdom’s veterinary profession. We, therefore, take a keen interest in all issues affecting the profession, including animal health and welfare, public health, regulatory issues and employment matters. We welcome the opportunity to respond to this consultation.

Our response is issued jointly with the British Veterinary Zoological Society (BVZS) and British Small Animal Veterinary Association (BSAVA). BVZS is the specialist division of BVA recognised as having responsibility for the care and welfare of exotic pets, zoo animals and wildlife. BSAVA exists to promote excellence in small animal practice through education and science and is the largest specialist division of BVA representing over 10,000 members. Further input was received from our Medicines Group and Policy Committee.

1. In light of the risks of diversion from legitimate uses and the harms identified in the ACMD advice, which option do you support?
   Option 1: Full Schedule 3 status under the 2001 Regulations as recommended by the ACMD
   Option 2: Place in Schedule 3 to the 2001 Regulations (but exclude application of safe custody requirements) ✓
   Option 3: Place in Part 1 of Schedule 4 to the 2001 Regulations.

Please explain why:
Small animal veterinary surgeons prescribe and dispense both pregabalin and gabapentin regularly under the ‘prescribing cascade’. The continuing use of these drugs is very important, as they represent clinically useful non-ulcerogenic, non-opioid analgesics particularly in dogs, and particularly in those suffering from neuropathic pain such as syringomyelia in Cavalier King Charles Spaniels. It is also used to treat refractory epilepsy in dogs. Evidence of beneficial effects is also accumulating in cats.


There is use of these medicines within the equine veterinary sector, though this is less than in the small animal sector. Veterinary surgeons who specialise in exotic animals also prescribe and dispense both medicines, gabapentin in particular. Key species in which it is currently being used in the UK include not only companion animals such as rabbit and large rodents but also large ungulates, including giraffe and elephant. Thus, quantities prescribed by individual veterinary surgeons can be significant. These medicines are not generally applied within the farm animal sector.

We recognise the increasing evidence of the misuse of these drugs, especially within at-risk populations such as known opiate abusers.\(^3\) Therefore, we support their greater regulation. As the source of these drugs, when they are misused, is usually by diversion of prescription drugs (rather than theft)\(^4\) we support option 2 as the proportionate response at this stage. The requirement for locked storage is not without its problems and costs as such storage is limited in size in most small animal veterinary pharmacies. Until there is better evidence that such storage would reduce the misuse of these drugs a risk-based assessment would suggest that such storage offers little benefit for the additional costs.

Based on this use, BVA believe that Option 2 provides the best route to balance the risks of diversion from legitimate uses and the harms identified in the ACMD advice with the impact on the ability of the veterinary profession to treat animals.

2. Do you agree with the impact assessment of option 1?
   Yes
   No ✓
   Don't know

If 'no' please explain why:

BVA notes that veterinary and animal health uses were not considered within the scope of the impact assessment. The financial implications for reclassification on veterinary practices and businesses were also not considered within the options appraisal. As noted above small animal, equine and exotic veterinary surgeons make use of these medicines.

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\(^4\) ACMD report on Diversion and Illicit Supply of Medicines Advisory Council on the Misuse of Drugs 15 December 2016
3. 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 1?

Yes ✓
No
Don't know

Please explain why:

A change to in regulation of these drugs to Schedule 3 would mean veterinary surgeons would face an additional consideration in their prescribing and storage: in line with other Schedule 3 drugs that are prescribed on a regular basis. We would ask that consideration be given so as not to constrain veterinary surgeons obtaining these medications in a timely manner for prescription to animals under their care.

As noted above these medicines are utilised by veterinary surgeons specialised in exotic animals for use in large animals, including giraffe and elephant. Thus, quantities prescribed by individual veterinary surgeons can be significant. Small animal veterinary surgeons will utilise these medicines on a regular basis. In both cases, the storage facilitates that will be needed to hold these medicines will not be insignificant.

4. To help inform the full impact assessment please quantify the additional cash cost per month of option 1 to you or your organisation.

Please provide details of cost per month:

£0 - £99
£100 - £199
£200 - £299
£300 - £399
£400 - £499
£500 - £1,000
Above £1,000, please state amount and any relevant breakdown:

The requirement for additional locked storage within the limited space of most small animal veterinary pharmacies will have additional costs. These additional costs are less likely to be recurrent costs as stated in the question. Rather this could mean a single large capital expenditure to provide additional facilities to store additional quantities of medicines under the proposed parameters. This will vary widely between veterinary practices given available space and equipment. This should be properly considered within the government’s impact assessment.
5. Do you agree that healthcare organisations or businesses will be able to accommodate pregabalin and gabapentin within current compliant safes?

Yes

No ✓

Don't know

If 'no', please explain why, including estimated costs to be incurred in acquiring a safe:

As noted above these medicines are utilised by veterinary surgeons specialised in exotic animals for use in large animals such as including giraffe and elephant. Thus, quantities prescribed by individual veterinary surgeons can be significant. Small animal veterinary surgeons will utilise these medicines on a regular basis. In both cases, the storage facilitates that will be needed to hold these medicines will not be inconsequential. Some veterinary pharmacies will be able to accommodate this change, others could find this change costly.