

Phenylbutazone and its availability in Ireland – prudent prescribing and dispensing

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BACKGROUND

Phenylbutazone (bute) is arguably the most potent and effective pain relieving agent available in equine medicine in this country. The difficulty with phenylbutazone is that it, or its metabolite, can cause aplastic anaemia in children. If a child were to consume an animal-based product containing even the minutest amount of bute or its metabolite then the child may develop aplastic anaemia. As the horse is deemed a food-producing animal and horsemeat is consumed in large quantities in Europe, the European Commission decided to remove phenylbutazone from the shelf and ban its use altogether.

A long and protracted series of negotiations ensued, led in no small part by Hugh Dillon MRCVS of Troystown Veterinary Hospital under the flag of what was then the Irish Veterinary Association. This culminated in a meeting with the European Commission in Brussels in November 1999 whereby an understanding was reached.

The Commission accepted that there existed the species of equine as an athlete as opposed to the equine as a food-producing animal. For its part, the veterinary delegation undertook that the horse would have an identity book (equine passport) that would clearly mark these equines as athletes and not intended for slaughter for human consumption. There was a promise that a) good records would be kept of the use of phenylbutazone along with external monitoring of its use, and that b) the product would not be handed out as if freely available. The rock-solid promise made that the Commission insisted upon is that the passport of each and every horse that ever received phenylbutazone would be clearly marked as not intended for human consumption.

The legislation is now in place (EU Comm Reg No 504/2008), stating that all horses in Europe must have an equine passport. The legislation goes further to state that any passport issued to an equine over six months of age will automatically be excluded from the food chain. Furthermore, the legislation states that duplicate passports issued to horses will be marked excluded from the food chain.

Veterinary Ireland made strong recommendations that all passports would be marked unsuitable for slaughter for human consumption unless otherwise stated. This was deemed to be a step too far, and so we have the situation that duplicate passports and passports to foals over six months of age, or in the calendar year following their birth are automatically deemed to be unsuitable for slaughter for human consumption.

PRESCRIPTION ONLY MEDECINES (POMS)

Phenylbutazone is a POM and can only be prescribed under the rules set out in the 2007 Animal Remedies Regulations. Those regulations set out clearly when a Veterinary practitioner can and cannot prescribe a medicine and dispense the same medicine for an animal under his/her care.

POM medicine usage hinges on the term 'animals under our care' and the regulations make reference to guidelines and to further governance under the Veterinary Council Guide to Ethical Veterinary Practice (in relation to prudent prescribing and dispensing). It describes when an animal is under our care. It also mentions having 24-hour veterinary emergency cover for those animals under our care, and that the cover should be real and not nominal. On top of all that, there is our own ethical behaviour and what we, as clinicians, feel is the appropriate and prudent use of such a product. We, as veterinarians, know how useful this product is. We know how much of it is used by our horse clients in this country. We also know it causes ulceration of the bowel in our patients. We are fully aware of the consequences of an outright European ban of the product if prudent dispensing is not observed. Because of that, and above any medicines or Council regulations, we never prescribe or dispense bute until we are absolutely certain that the animal receiving the product has a passport clearly signed (Section IX of medicine section of passport) by both owner and veterinary surgeon, stating that the animal is permanently excluded from the food chain.

We go further by simply prescribing only to those horses that we have seen and have clinically deemed to require the product. We only dispense sufficient product as befits the clinical condition for which it is being used, ie, two-to-three days or seven-to-10 days as we deem necessary. We are continually vigilant to inform our clients that unused excess powders are not for use in another animal. We also push, wherever necessary, to ensure that every horse on the premises of our 'buted' horse has a passport and, where possible, that all passports are signed to exclude the horses from the food chain.

Reluctance to exclude the horse by an owner may need a gentle prompt. There are strict rules in place in this country in relation to food-producing animals. All medicines used in these animals must be recorded, including wormers, vaccines, antibiotics, etc. These records must be available for inspection by Department of Agriculture

officials for up to five years. All food-producing animals on a holding are subject to visitation by Department officials and each food-producing holding will need to be licenced in accordance with beef-rearing enterprises. By signing the passport this requirement is removed.

Leakage

It is a statement of fact that if the European Commission on its audit of this country find evidence of bute use in animals not excluded from the food chain, then the product will immediately lose its licence Europe-wide.

If samples prove positive for phenylbutazone or its metabolite in equine meat of Irish origin, it will be traced back, and the prescribing veterinary practitioner will be in the firing line of prosecution.

Insurance cover for such costs hinges on whether the veterinary practitioner's actions were deemed similar or in line with that of his/her peers. Some scenarios of phenylbutazone dispensing may arise as follows:

Example 1:

A good client who brings her dogs to the clinic on a regular basis has an old pony at home. The pony is retired now, but has an old arthritic joint that gives it trouble now and again. The practice does the flu and tetanus visit along with a teeth rasp and wormer, but was not the practice that took X-rays or diagnosed the arthritis. In fact, the arthritis was only mentioned when the owner was in with her golden retriever for a check-up. She asks for a box of bute for the pony for whenever it is lame.

Prudent prescribing, in this case, means that the vet must decide if the other practice that took the X-rays is not best placed to prescribe the bute. If that practice is no longer looking after the animal, then the vet must decide if the animal really requires the product. To do that, he/she must satisfy himself/herself that the arthritis exists and is causing pain that needs medication in the pony. This will require a clinical examination. If, on the last flu and tetanus visit a few months previously, lameness was noted, then the vet may prescribe, based on the owners update, that this condition is again causing pain and needs some phenylbutazone to medicate it. But a box of bute (100 sachets – sufficient for up to almost a year's medication of the pony) is never prescribed and dispensed. In the case of the old pony, prudent prescribing means sufficient medication to cover a reasonable period of time and if the pain persists, then a further clinical examination may be necessary. We should always ask ourselves if more than 10 days' medication is needed in this case. Before prescribing, have we checked and signed the passport to exclude it from the food chain? Don't forget correct and clear labeling at all times.

Example 2:

The son of your best dairy client walks in to pick up powders for calf scour and a box of bute for the hunter. The practice does not do the equine work on that farm but are well aware of the hunting tradition of that family.

They are a responsible farming family who do their work in a professional way. The other vet gave them bute before, but it is much more convenient to collect a box at this practice.

Prudent prescribing in this case is not to prescribe or dispense at all. The horse is not under our care, and it's best to ask the client to go to the equine practice for equine medication. Even if our practice has a substantial equine section, and we would love to do the equine work for this hunting dairy client of ours, we don't begin our equine business with a client by handing out a box of bute.

We start by saying bute is a coveted medicine in the veterinary armoury and that we would suggest we see the horse when we are back out to check on the calf with scour. Then we can clinically assess the need; we can clinically prescribe the product; we can examine and sign the passport (don't rely on his word that he got bute elsewhere, and therefore the passport is signed – always check it before dispense) and duly dispense the correct amount.

Example 3:

The husband of our companion animal client comes in to pick up the dog after a bitch spay. We are a companion animal practice but are aware that this man is heavily involved in the equine world, and is also a committee member of the local gun club. His influence over many gundog owners is immense and he has asked for 10 bute sachets. We don't do much horse work, but we do have 10 bute that are fast approaching their expiry date. He says that his horse passport is signed to exclude him from food production, and that his horse vet is away on holidays. He's also speaking at the gun club dinner later that evening, and would be recommending the practice to members on foot of the excellent operation and care on his wife's dog. And if we could just give him 10 bute, he would be on his way.

Prudent prescribing tells us we cannot even contemplate dispensing medication in this case. Best practice would recommend disposing of those 10 sachets if very little equine work is carried out by the practice.

Example 4:

An equine practice in the Curragh has just begun services with a big client and we are all to put our best foot forward. There were 10 yearlings for castration, five mares for scanning, and a box of bute required in case any of the horses get a knock or are lame.

Prudent prescribing says no, even though we wish to make a good impression. Check all passports and sign them first. Explain how coveted this medicine is. Prescribe and dispense only for a known horse with a known condition. Bute is not for storage for a rainy day. The client may certainly have some bute, but he must specify first which horse it is for; check and sign the passport; clinically decide that bute is required, then prescribe and dispense the correct dose for the correct length of time, always pointing out that unused product is not for incidental use in another animal.

We must also remember that the Department of Agriculture can source which practices are ordering bute and can ask to see our records to see if it being correctly dispensed.

SUMMARY

We are blessed at present that the European Commission allows us to identify our horses as athletes. As well as many other equine medicines, phenylbutazone can only be used in non-food producing animals. Covet the product. Check and sign the passports. Continuously feed the information to equine owners that bute is a restricted product. Never allow 'rainy day storage' of the bute powders on a holding.

Use your veterinary expertise and ethical behaviour of the highest standards when prescribing the product.

One child's bone-marrow illness could be traced to a meat product which could be traced to an owner and a

vet who prescribed bute. Label the product clearly. Refrain from handing out a box. It needs to be some sort of extraordinary scenario that requires a horse to receive almost a year's medication for chronic laminitis. What's wrong with asking the client to come back in a month or two if the first 20 powders are all gone?

Almost 70% of equine medicine usage in veterinary practice consists of products not authorised for the treatment of horses intended for human consumption (ref: Dechra Veterinary Products booklet promoting responsible phenylbutazone use).

If we cannot carry out prudent prescribing for phenylbutazone then one wonders will we lose all the above-mentioned products also.

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CONTINUING EDUCATION: READER QUESTIONS AND ANSWERS

1. WHEN IS THE HORSE CONSIDERED TO BE A FOOD PRODUCING ANIMAL?

- a) After two years of age
- b) After six months of age
- c) When retired permanently from competition
- d) At all times unless passport is signed to exclude from the food chain

2. WHEN CAN PHENYLBUTAZONE BE ADMINISTERED TO A FOOD-PRODUCING ANIMAL?

- a) Once it has a passport
- b) When less than six months of age
- c) In emergency cases until a decision is made on whether to slaughter or not
- d) Never, unless it is a horse that has a passport signed to exclude it permanently from the food chain

3. WHAT FORM OF PHENYLBUTAZONE (INJECTABLE, ORAL POWDER, PASTE) CAN BE USED IN CALVES LESS THAN SIX MONTHS OF AGE?

- a) Injectable only
- b) Injectable and oral paste
- c) Oral paste or granules
- d) None. Cattle are always considered food-producing animals. The horse is the only food-producing animal that is allowed a special derogation to permanently exclude that individual horse from the food chain;

4. HOW MANY SACHETS OF "BUTE" GRANULES IS CONSIDERED A REASONABLE AMOUNT TO DISPENSE TO AN OLD PONY WITH NO PASSPORT?

- a) Six sachets
- b) Twelve sachets
- c) Three days' emergency supply
- d) None. All equines must have a passport. The passport must be signed to exclude from the food chain before any "bute" is dispensed, even in emergencies

5. WHEN DISPENSING PHENYLBUTAZONE TO A THOROUGHBRED HORSE, WHAT MUST BE PARAMOUNT IN OUR MINDS?

- a) That the horse must not race for eight days after cessation of the administration of the powders
- b) That the feed bucket used to mix the powder is not passed on for use by another horse in training
- c) All of the above after the passport is examined and signed to exclude the animal from the food chain
- d) None of the above

6. WHEN DISPENSING PHENYLBUTAZONE TO A THOROUGHBRED HORSE, WHAT MUST BE PARAMOUNT IN OUR MINDS?

- a) When an owner gives a reasonable explanation as to why he needs the powders
- b) When a client of the practice gives a favourable character reference for the person asking for the product
- c) When contact has been made with the horse owners' own bona fide veterinary practitioner who instructs how much, what dosage, and clarifies that the horse passport is verified as excluded from the food chain
- d) Never, unless the animal is clinically examined, assessed, and the passport signed to exclude the animal from the food chain

Answers: 1: D, 2: D, 3: D, 4: D, 5: C, 6: C