# Animal medicine seizure notice: Parcel addressed to Castlederg, County Tyrone

News story

Details of seizure notice served following a parcel addressed to premises in Castlederg, County Tyrone stopped at a Belfast Depot.

The following veterinary medicines were identified by a courier company based at a Belfast depot. The products were then detained and subsequently seized by the Department of Agriculture, Environment and Rural Affairs (DAERA).

This parcel was addressed to residential premises in Castlederg, County Tyrone and was shipped from Australia. The parcel contained:

- 25 x Folic Acid and Vitamin B12 injection (100ml)
- 10 x COpHOS B injection (100ml)
- 5 x Mitachondral injection (100ml)

These products were labelled for the treatment of horses and dogs. They are not authorised as veterinary medicines in the UK.

The medicines were seized under Regulation 25 (Importation of unauthorised veterinary medicinal products) of the Veterinary Medicines Regulations 2013.

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# Reminder about sending post to the VMD

News story

A reminder about what to do when sending information and payments to the VMD whilst we continue to work remotely.


As our staff continue to work remotely in line with Government advice, we cannot guarantee that any item sent to the VMD by post will be processed promptly. There may therefore be delays in taking action in response to any information you send us in hard copy format.

If your enquiry relates to a payment, please see our application fees page for a reminder of our bank details and finance contact. Please, wherever possible, do not send cheques and instead use a bank transfer.

Please also, note that we are unable to accept credit card payments.

The VMD therefore requests that, wherever possible, you send information to us electronically and do not send post to our office. If you have to submit hard copies of information or cheques please notify us first at postmaster@vmd.gov.uk. We will then advise you accordingly.

Thank you for your cooperation.

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# Environment Secretary speech on gene-editing consultation: Oxford Farming Conference 2021

It is a real pleasure to be able to address this year's virtual Oxford Farming Conference – obviously the 75th such conference so an important milestone. The new national lockdown restrictions, which have been announced in recent days are a reminder that we are far from out of the woods as we fight the coronavirus pandemic.

Our key workers in the NHS will be tested in the coming weeks. And those key workers in the food supply chain, working on farms, in food factories, in the distribution chain and in supermarkets will again be performing a vital function to ensure that the nation is fed while others stay at home.

The events of the last year have highlighted the importance of domestic food production to our food security and testing times such as these are a reminder to society about the jobs which really are important.

There is a key difference between this current lockdown and the first one. Technology has emerged with a solution. This week the AstraZeneca vaccine developed in Oxford has started to be deployed. The development and rapid authorisation of both the Pfizer and now AstraZeneca vaccine has been an incredible feat of science. And this is an area where the UK has global leadership.

And it is science that I want to focus on today because the UK is home to some of the world's leading agricultural research institutes.

We have the John Innes Centre in Norwich with its focus on agricultural technology, the work of the National Institute of Agricultural Botany with its work on sustainable agronomy and climate resilient crops, the James Hutton Institute in Scotland with its pioneering work on vertical farming and sustainable land use.

Then there is the ground-breaking work done at Aberystwyth on grassland management and livestock, the work of the Rothamsted Research on genetic technology and of Cranfield University's work on soils… to mention but a few.

The expertise that we have here in the UK is of global importance and we are global leaders in many areas of research.

Take wheat – it is not only the world's oldest major agricultural crop, it is also the most widely grown, it is Britain's largest crop, and it supplies a fifth of all human calories worldwide. But it is also affected by climate change.

UK funded research is leading efforts to address that threat, including UKRI's Designing Future Wheat initiative and Defra's Genetic Improvement Networks.

I have said previously on many occasions, that, as we consider future policy, what we really need to achieve is a fusion of the traditional principles of good farm husbandry with the best technology available to us in the 21st century.

The intensification of agriculture during the 1960s and 1970s led to higher yields, brought more land into cultivation and delivered the post war imperative to boost food production.

However, it also led to a sharp increase in the use of synthetic fertilisers which, in turn increased carbon emissions; it led to the loss of thousands of miles of hedgerows which are the single most important ecological building

block in our farmed landscape; it led to the ploughing up of traditional meadows and the loss of the ecology contained within them; it led to an increase in the use of synthetic pesticides which had impacts on non-target insect species too; latterly it led to greater specialisation on farms leading to more pressure on water quality in livestock areas and the unsustainable exploitation of soils in arable areas.

We now know that the impacts of these changes caused a sharp decline in farmland bird populations and other measures of biodiversity. The pace of decline has certainly slowed in recent years as protections were increased and policy started to refocus, but reversing the trends has proved stubbornly difficult to achieve.

But imagine if we could retrace our steps back to the late 1960s and plot a different course, the benefit of hindsight. What might it look like and what might we do?

Perhaps we would have placed more value on the traditional meadows and the hedgerows and rewarded farmers for managing them well.

Perhaps we would have encouraged more sustainable management of soils with more emphasis on mixed systems and less on specialisation; perhaps we would have supported more extensive systems of farming that relied on fewer external inputs.

And if it were available to us then, perhaps we would have seen the potential to reconcile sustainable farming with vibrant and profitable food production through the deployment of genetic resources.

Genetic diversity is what gives life itself resilience. The billions of genes that exist in the millions of plant and animal species on our planet are a memory of all the challenges that have been encountered in the past and can help us prepare for the challenges of the future.

There are genes that cause wild grasses to search deeper in soils for their nutrients, there are genes that give plants natural resistance to fungal diseases, there are genes that enable plants to synthesise natural hormones that deter certain insect pests and genes that enable plants to cope better with water stress. What we have now that we did not have in the 1960s, is the ability to harness the genetic resources that mother nature has provided to tackle the challenges of our age and to replace some of the harmful practices that led to environmental harm in the past.

Twenty years ago, there was much debate about genetically modified crops. It is fair to say that there was understandable public concern about moving genes across natural biological boundaries – or transgenesis.

In particular, it will always be important to have a robust and precautionary regulatory system in place to govern genetic modification when transgenesis is involved.

Nature has created natural processes to buffer the movement of genes across biological boundaries through the compatibility of flowers from different

plant species. Even when methods like grafting or budding are deployed, biological compatibility between the rootstock and the scion really matters.

However, what we have learned since that initial GM debate is that cisgenesis – where traits are moved within a species or genus of plant – is also powerful, but raises far fewer ethical or biological concerns.

Techniques such as gene editing are really a natural evolution of conventional approaches to plant breeding. For some seventy years, plant breeders have used chemical and radiation treatments to generate random mutations in genes in the hope that these might provide traits that are useful for plant breeding. For decades, we have had F1 hybrid breeding techniques that were designed to create far greater genetic consistency in plant varieties grown commercially.

What we are now able to do through techniques such as gene editing is to more accurately move traits within the same species in a way that could happen naturally and which therefore respects the rules of nature.

It gives us the power to evolve plant varieties with particular traits far faster than was ever possible with conventional breeding and this opens up huge opportunities to change our approach and embrace sustainable farming.

It creates the potential to breed plant varieties that have natural resistance to fungal diseases and to evolve traits at a pace that keeps up with the evolving pest.

It creates the ability to breed crops and grasses that perform better with fewer inputs reducing costs to farmers and reducing impacts on the environment, and it creates the ability to breed plants that can adapt to the challenges of climate change.

Water scarcity will be a major impact of climate change and it will mean that land in some parts of the world that can currently be farmed will become unviable in the future unless plant breeding technology is able to keep pace with the challenge.

Two years ago, the European Court of Justice ruled that cisgenic techniques using gene editing should be treated the same as genetic modification under EU law.

That means that new technology would be stifled from the beginning because the EU’s procedures around gene editing are notoriously restrictive and politicised such that no one trusts the integrity of the process. The ECJ judgement was based on legal interpretation, not based on science. The UK opposed the judgement. Even countries like Germany with more scepticism about GM, recognised that gene editing was very different and an important new technology to meet the challenges of the future.

As an EU member, we obviously had no choice but to slavishly adopt the judgements of the ECJ, however irrational and flawed they might be.

Now that we have left the EU, we are free to make coherent policy decisions

based on science and evidence and it starts today with a new consultation on proposed changes to English law that will enable gene editing to take place, so that we can achieve a simpler, scientifically credible regulatory framework to govern important new technologies.

If we are to deliver the ambitions we have for the environment and make space for nature, then we must rebalance the incentives in our future agriculture policy to encourage sustainability, but we must also use the tools that science provides to ensure that profitable food production and sustainable land management go hand in hand.

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# Safety review of epilepsy medicines in pregnancy – women who may become pregnant urged to discuss treatment options with their doctor

Lamotrigine (Lamictal) and levetiracetam (Keppra) have been found to be safer than other antiepileptic drugs in pregnancy. The MHRA advises patients not to stop taking their current medicines without first discussing it with a healthcare professional.

The review by the Medicines and Healthcare products Regulatory Agency examined safety data for risks of major birth defects or abnormalities and concerns with the child's development including learning and thinking abilities for other key antiepileptic drugs. It found that a number of these epilepsy medicines may be associated with some increased risks in pregnancy.

Valproate (Epilim) is already known to be seriously harmful if taken in pregnancy and should only be prescribed to a woman if a pregnancy prevention plan is in place. Importantly, two antiepileptic medicines in particular, lamotrigine (Lamictal) and levetiracetam (Keppra), have both been found to be safer than other antiepileptic drugs in pregnancy. The MHRA advises patients never to stop taking their current epilepsy medicines without first discussing it with a healthcare professional.

**Dr Sarah Branch, Director of MHRA's Vigilance and Risk Management of Medicines Division said:**

> Patient safety is our highest priority, and we are committed to making sure women are aware of the risks of taking certain epilepsy medicines during pregnancy, particularly valproate.
>
> We have shared this important review with doctor and nurses so they

can use it to inform discussions with their patients.

If a woman is planning to become pregnant, and is taking a medicine for epilepsy, even if this is some time in the future, it is very important that she should discuss with a healthcare professional the right treatment for her, taking into account the results of this review.

It is vitally important that women don't ever stop taking any epilepsy medicine without discussing it first with a healthcare professional.

**Louise Cousins, Director of External Affairs at Epilepsy Action said:**

We're pleased to see that this review has taken place. This information has been provided to doctors and nurses, so that women can be made aware and supported to make informed decisions about their care and treatment.

No woman or girl should be taking an anti-epileptic medication without them, or their family, being aware of the risks as the consequences can be devastating.

**Dr Jo Mountfield, Consultant Obstetrician and Vice President at the Royal College of Obstetricians and Gynaecologists said:**

We welcome the MHRA's safety review of epilepsy medicines in pregnancy and any associated risks.

It's important to discuss with your doctor if you are considering stopping medication for long-term conditions completely or altering the dose as this can pose a serious risk to your health.

We advise that women with epilepsy should seek advice and information from their doctor pre-conception as well as throughout their pregnancy. This will help ensure women can make well informed decisions about planning their pregnancy and any concerns they have about their medication.

**Paul Chrisp, Director of the Centre for Guidelines at NICE, said:**

NICE welcomes this move from MHRA to ensure women are fully aware of the risks of taking certain epilepsy medicines during pregnancy. We've already made changes to our guidelines to reflect MHRA's earlier advice about the use of sodium valproate.

> It’s important that everyone affected by these latest changes is made aware of them as soon as possible. We’re therefore taking steps to review our guidelines where these medicines are recommended, including the assessment and management of bipolar disorder, depression in adults, and antenatal and postnatal mental health to reflect this important advice.
>
> Our guideline on the diagnosis and management of epilepsies is currently being updated as part of our normal review cycle; in the meantime we will ensure the new advice is clearly signalled within the existing guideline.

Antiepileptic drugs are crucial to control seizures and other epilepsy symptoms. Untreated epilepsy can cause harm to both mother and unborn baby.

The review on the use of epilepsy medicines in pregnancy was carried out by the Commission on Human Medicines (CHM) following earlier reviews of the antiepileptic medicine, valproate, which is known to be harmful if taken during pregnancy.

The MHRA is asking clinicians to use the review’s findings to discuss the potential risks to the baby associated with epilepsy medicines and untreated epilepsy during pregnancy, and to review patients’ treatment according to their clinical condition and circumstances. The MHRA has produced a safety information leaflet to help with this discussion.

The MHRA has a Valproate guidance page with more information about the risks and regulatory action taken to date.

## Notes to Editor

1. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care.
3. The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care.
4. The review was carried out by the Commission on Human Medicines (CHM) following earlier reviews of  the antiepileptic medicine, valproate, which is known to be harmful if taken during pregnancy. If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders and approximately 1 in 10 are at risk of birth abnormalities (birth defects). For this reason, in 2018 the MHRA introduced the valproate pregnancy prevention programme and is committed

to reducing the use of valproate in pregnancy to an absolute minimum. The review found that other epilepsy medicines may be associated with some increased risks of birth abnormalities or other effects on the baby. However, no epilepsy medicines reviewed are thought to have a risk greater than that of valproate.

5. Drug Safety Update, Public Assessment Report and safety leaflet.

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# Weston-Super-Mare woman convicted of making a fraudulent claim

Press release

Lisa Pearce prosecuted by the Security Industry Authority (SIA), pleads guilty to fraud at Bristol Crown Court.

On 18 December 2020, Lisa Pearce of Weston-Super-Mare pleaded guilty to fraud at Bristol Crown Court; Pearce's sentence was 180-hours of unpaid work which must be completed within two years. Pearce was prosecuted by the Security Industry Authority (SIA).

Pearce was formerly an SIA licensed Door Supervisor and her licence expired on 7 August 2018.

She applied for a new licence on 3 February 2019 and there was a delay in processing Pearce's licence application.

Pearce received her licence on 21 August 2019 and the SIA returned her application fee and advised her about the compensation for a loss of earnings. Pearce made a claim against the SIA for the loss of earnings during the period. Applicants have the right to seek compensation if there is a delay to their application. The SIA will consider a request for compensation for loss of earnings, if a claim is justified and legitimate.

The SIA requested Pearce to submit evidence of the loss of earnings by

proving her historic earnings as a security operative. The documents Pearce submitted aroused the SIA's suspicions, it sought to verify the documents with her employer but was unable to.

Pearce submitted documents and payslips for the following amounts:

- November 2018 – £1,379.50
- December 2018 – £1,379.50
- January 2019 – £1,286.50

On 30 August 2019 Pearce was interviewed under caution and admitted that she had downloaded template payslips from the internet and completed them to use as an illustration and admitted creating fraudulent articles.

Nathan Salmon, from the SIA's Criminal Investigations team, said:

> Lisa Pearce sought to defraud the SIA by providing false documents. Licensees have a right to compensation if there is a case, but if there is an attempt to defraud, then the SIA will prosecute. Pearce tried to gain financially from her loss of earnings claim by supplying fraudulent wage slips. Pearce had her door supervisor's licence suspended by the SIA pending the outcome of the prosecution. She has now lost that licence due to her criminal record.

During the prosecution, His Honour Julian Lambert, said in his sentencing remarks:

> Pearce's decision to make the false claim for loss of earnings to the SIA was a stupid one. Her lies have caught up with her and now she must pay the price. That price is the loss of a job that she loved and the means to support herself.

Notes to editors:

- by law, security operatives working under contract must hold and display a valid SIA licence
- read about SIA enforcement and penalties
- the offence mentioned in the above news release is: Fraud Act 2006: Section 7 (Making or supplying articles for use in frauds)

Further information:

- The Security Industry Authority is the organisation responsible for regulating the private security industry in the United Kingdom, reporting to the Home Secretary under the terms of the Private Security Industry Act 2001. Our main duties are: the compulsory licensing of individuals undertaking designated activities; and managing the voluntary Approved Contractor Scheme.

- For further information about the Security Industry Authority visit www.gov.uk/sia. The SIA is also on Facebook (Security Industry Authority) and Twitter (SIAuk).

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