Press release: South West Water to pay £142,524 for Devon and Cornwall breaches

South West Water Ltd has been ordered to pay more than £142,000 in fines and costs for discharging poor quality effluent from two of its sewage treatment plants. The prosecutions were brought by the Environment Agency.

The offences were committed in Denbury, Devon and Praze an Beeble near Camborne, Cornwall where the company breached permit conditions by allowing inadequately treated effluent to enter nearby watercourses.

Strict limits are set on effluent discharged from sewage treatment works to ensure they don't adversely affect receiving watercourses. It is the responsibility of the site operator to ensure a treatment works operates in accordance with its permit. They must carry out regular maintenance and repairs.

At Denbury, treated effluent is discharged into the Halwell Stream. Between September 2015 and June 2016, four samples tested for ammonia, suspended solids and Biochemical Oxygen Demand (BOD) exceeded the quality standards laid down in the site's permit. The treatment works is only permitted two exceedances in any 12 months so the additional discharges made in March and June 2016 were offences.

The court was told the filter bed rotating arms at the site failed to operate effectively over a number of months. This coincided with a time when the site was not visited every day and alarms were not working reliably.

The sewage treatment works at Praze an Beeble requires a lot of maintenance and is permitted to discharge only a very limited amount of ammonia. Every month South West Water must take a sample of the discharge and notify the Environment Agency of the result.

In May and August 2016 the amount of ammonia discharged exceeded the amount allowed by the permit.

When further inquiries were made by the Environment Agency, it transpired that the site's online ammonia monitor had recorded that too much ammonia had been discharged from the treatment works for some 15 days in April 2016 as well.

In May, part of the site was not being cleaned often enough and equipment needed repairing. In August, part of the site had been blocked by moss, blanket weed and sludge. South West Water said the monitoring equipment had not always worked accurately in April.

Mark Pilcher of the Environment Agency said:

> Water companies must ensure effluent is treated to a sufficiently high standard to protect the environment. Regular maintenance of sewage treatment works helps with the early detection of faults and allows repairs to be made in good time before treatment deteriorates to the point where a site breaches its permit.

Appearing before a district judge at Bodmin Magistrates' Court, South West Water Ltd was ordered to pay a total of £142,524. The company had earlier pleaded guilty to three charges (two for Denbury and one for Praze an Beeble) of breaching Regulation 38(2) of the Environmental Permitting (England and Wales) Regulations 2010.

The fine for Denbury was £80,000 with £4,993 costs plus a £120 victim surcharge. The fine for Praze an Beeble was £53,334 with £3,957 costs plus a £120 victim surcharge. The case was heard on 3 August, 2017.

Speech: Speech given by Lord O'Shaughnessy on Brexit and medicines regulation

Introduction

Good afternoon, and thank you for giving me the opportunity to come here to speak to you today at the 7th joint BIA / MHRA conference, and to allow me to set out the Government's thinking on the opportunities and challenges facing the life sciences sector as we move towards Brexit.

I want to start by thanking Steve and the BIA for their support and challenge since I took up my role, as well as Ian and all of the officials at the MHRA for their continued high quality policy support to me.

I hope today to be able to detail some of the work that is going on to help shape our future relationship with the EU, and in particular define the principles which are informing our approach.

I also want be very clear, right at the start of this speech, that the Government recognises that we start from a historically unique position in these negotiations – close regulatory alignment, trust in one another's institutions, and a spirit of cooperation stretching back decades.

Our top priority in negotiations in this area is to secure ongoing close collaboration between the UK and the EU, with the needs and rights of patients always our paramount concern.

As everyone in this room will know, the UK has much to offer. We are a scientific, regulatory and industrial centre of excellence. I had the opportunity to see this during a visit yesterday to the Clinical Research Facility at UCLH, where NHS patients were the first in the world to receive innovative new medicines as part of globally leading, cutting edge trials.

I am incredibly proud of the superb work done by the whole of the life sciences ecosystem: UK companies, research institutions, universities, hospitals and charities.

We have a proud history of being a forward looking, innovative and risk taking nation, able to work at the cutting edge of science to advance the cause of medicine.

From Edward Jenner's work on developing the world's first vaccine through to our ambitious plan to sequence 100,000 genomes, the UK has played a major role in global medicine.

It's remarkable that currently 25% of the world's top 100 prescription medicines were discovered in the UK, and the UK undertook almost 20% of all research work carried out within EU health programmes between 2007-2016 was undertaken on these shores.

The UK life science sector is globally leading, with the strongest clinical development pipeline in Europe, and more than a third of all the biotech venture capital in Europe, which is more than any other European country.

Our success is built on a world class science base that is the most productive of any in the G7, supported by over £4 billion of funding per year from Government and Philanthropy. We are, and always have been, a medical innovation powerhouse.

Brexit is, in this Government's view, a once in a lifetime opportunity to build on our existing strengths – and we should look upon the challenge with optimism and hope. There is a collective determination and will to make a success of Brexit.

However, it would be Panglossian not to recognise that challenges will confront us in the years to come, nor to underestimate the complexity of the task.

Today, I will set out in practical terms the Government's position on medicines regulation, trade and support for the life sciences sector in the UK.

We are absolutely clear that three key principles must underpin any future relationship with the EU:

- First: patients must not be put at a disadvantage;
- Second: the UK will continue to play a leading role promoting and

ensuring public health – both in Europe and around the world; and

- Third: industry must be able to get their products into the UK market as quickly and simply as possible, with the UK and Europe at the forefront of medical innovation.

Medicine regulation

Let me turn first to medicines regulation. To reiterate the principles above, our top priority for life sciences during the negotiations is to protect the safety of patients and ensure the integrity of pan-European public health systems.

I want to give this promise: no matter what the outcome of the negotiations – on basic patient safety and public health issues – the UK will be, as it always has been, a willing and reliable partner for Europe.

The people of Europe would expect nothing less, and it is incumbent upon those on both sides of the negotiating table to ensure this continues.

Building on this base of public health collaboration, you will have seen the letter from Jeremy Hunt and Greg Clark in the Financial Times last week.

My colleagues gave a crystal clear, public statement of our desire for deep and close working relationship with the EU on medicines regulation after Brexit. That approach is supported across Government.

Patients across the EU27, including those in the UK, have been well served by our close cooperation for many years.

The cooperation has seen major improvements in expediting patients' access to new medicines. We have also pioneered adaptive approaches to clinical trials and conditional approval to meet medical need.

The MHRA pioneered the adoption of the 'Early Access to Medicines' scheme, which enables people with serious life threatening conditions to get new medication before all approvals are finalised, where there is a clear medical need.

This has made a huge difference to patients, and has led the way for the EMA to adopt similar principles.

It is also right to acknowledge that the UK's existing relationship with the EU is mutually beneficial. The MHRA play a big role in this, but it is right too that we should acknowledge the benefits we have gained from the pan-EU burden sharing approach to medicines regulation. This arrangement has allowed the UK and NHS patients to benefit from outstanding scientific expertise from across Europe.

Sharing this expertise across the EU has led to significant public health and safety improvements. Knowledge and innovation is not and cannot be exclusive

to one country.

Patients across the EU27 and the UK will be better served if together we continue the strong, effective technical collaboration that accelerates scientific advancement and ultimately benefits patient wellbeing.

It is worth remembering that in many cases rules are based on global requirements. For example, the Pharmaceutical Inspection Co-operation Scheme leads the international development of voluntary Good Manufacturing Practices for medicinal products. As part of our vision for an outward facing UK we will continue to play a leading role in such international forums. This is what we mean by a new, deep and close partnership with the EU.

And I know it is what industry wants too, which is why I am asking for your continued support in helping to achieve it. The recent letter from Trade Associations across Europe to Michel Barnier and David Davies on this topic was an important first step.

We need you to lobby for your views on what success looks like to both the UK and the EU27. I passionately invite you to make your voice heard throughout this debate so that your views can be taken into account.

I also briefly want to address the alternative scenario.

As everyone in the room will know, not all negotiations succeed.

In the event that it is not possible to reach a deal that secures ongoing, close collaboration between the UK and Europe, we will set up a regulatory system in the UK that protects the best interests of patients, and supports industry to grow and flourish.

We will ensure that our system is robust, efficacious and does not impose any additional bureaucratic burdens. Our successful past should give us confidence in achieving a prosperous future, whatever form it takes.

I want to be clear, this is not a threat to the EU27. But I must be honest and transparent, that if it is not possible to secure close collaboration, we will of course look to put in place an effective system and work with international partners in a way that best protects patients and supports industry and innovation.

To summarise, like all of you, I am enormously excited at the range of medical innovations we will see over the coming decades. I sincerely hope it will be possible for the UK and the EU to work together to ensure patients have safe access to them, whether they are in London or Ljubljana, Manchester or Malmo.

Trade

However, regulation isn’t our only consideration as we leave the EU.

The UK wants to see zero tariffs on trade in medicines and medtech and to minimise the regulatory and market access barriers for medicines, med tech

and medical research services.

We want to have a new customs agreement with the EU that supports these objectives, and we have an open mind about the form of that agreement. This is central to our principle of ensuring that UK companies have the maximum freedom to trade with and operate within European markets – and to let European businesses do the same in the UK.

The UK Government wants such an arrangement to help make sure that medicines and devices reach patients when and where they need them and that product integrity is ensured.

The UK and EU have a shared objective in the negotiations: to protect the health of patients, and to ensure safe and timely access to medicines and devices. Simply put, far more unites our interests in this area than divides us.

This international outlook is a reminder of the manner in which the UK life sciences industry has proven itself able to adopt a truly international approach to providing high quality products, in demand across the world.

We will also be ambitious in pursuing new trading relationships globally, to ensure that pharmaceutical products developed and manufactured in the UK can be exported to all corners of the planet.

Equally vital to global trade is the global movement of people. I greatly value the contribution of those from the EU and around the world who work in our NHS and in our life sciences industry.

We recognise that medical research and development is a mobile, global business – and we want the best and the brightest, wherever they are from – to be able to study, work and innovate in the UK.

We know that for every Ronald Ross, there will be a Louis Pasteur, and indeed for every Ian Hudson, there will be a Guido Rasi. Whatever nationality – we want Britain to attract the best and the brightest.

I want to assure you that as the Brexit process progresses, we will continue to work closely with industry and trade bodies, including the BIA, to plan our policy for a prosperous future as a great, global trading nation.

The future of life sciences

Finally, I want to outline my vision and plans for the future of the life sciences industry in Britain. I am delighted that Sir John Bell has been leading the sector in developing a Life Sciences Industrial Strategy.

This will set out an ambitious vision for the life sciences industry to be a global hub and reaffirm the UK’s position as a centre of clinical research and medical innovation.

The Government looks forward to continuing to build on this, working together with industry to agree an ambitious, long term Sector Deal.

This is being developed in the context of the Cross Government Industrial Strategy, which was published in January.

In that document, we prioritised life sciences as a sector with the potential for an early Sector Deal. This offers industry and government the opportunity to agree an ambitious set of measures that will allow the UK to strengthen its position as a world leading centre for the life sciences.

It will also complement the Government's upcoming response to the Accelerated Access Review. I know some of you will feel that the response to Sir Hugh Taylor's review has hardly been accelerated itself, but that was because I want it to be the ambitious and transformative plan it should be, rather than another incremental change.

I recognise how challenging it can be to get innovations from the bench to the bedside in the NHS. The time it takes can be a cause of great frustration to innovators who feel they can make a real difference and see the NHS as an opportunity to develop and test their products – which are often much needed by patients and clinicians.

Therefore we need to do better. Much better.

We want the best innovations to come through quickly and improve the lives of patients, support the NHS and help create more jobs for the UK economy.

To underline our commitment, I am pleased to announce today that the Department of Business, Energy & Industrial Strategy and the Department of Health will be providing up to £86 million to support innovators in getting life saving products to patients faster and more efficiently. I would like to thank Lord Prior and his team for their contribution to this agenda.

The funding is split into four, targeted packages that together address barriers to product development, real world testing and uptake in the NHS:

- First, we shall establish a £35 million Digital Health Technology Catalyst which will match fund the development of modern day digital solutions for the NHS.

- Second, we are committing up to £6 million over the next three years to support SMEs with innovative medicines and devices in gathering real world evidence of their cost-effectiveness in a clinical setting. This will help to inform their final development and the healthcare system's purchasing decisions.

- Third, the government will support innovators and the NHS to take up innovations at the local level. We are making £39 million of funding available to the Academic Health Science Networks, enabling them to support local assessment and promote diffusion

- Finally, we will support the NHS to adopt and integrate these new technologies into everyday practice through a £6 million Pathway Transformation Fund.

This significant financial commitment underlines our on-going determination to making sure we continue to fund innovation to keep the UK at the forefront of the life sciences sector internationally. I am determined that our full response to the Review, as well as our Sector Deal, will set out a very ambitious way forward.

Conclusion

I hope that by setting out our clear principles for Brexit, and underlining our significant support for the Life Science sector – as demonstrated by our commitment of up to £86 million in funding to support innovation and change – you are left with a clear understanding of where this Government's priorities lie.

We have challenging but exciting times ahead of us, and we have a superb opportunity to reinforce the UK's position as a global centre of excellence for Life Sciences – collaborating and working closely with our partners in the EU and internationally.

I am proud that the Government is able to work so closely with industry, and am pleased with the very positive level of engagement and debate that has occurred so far between us.

I am confident that the Life Science industry will be able to make the most of the opportunities offered by Brexit, and help reaffirm the UK's position as a global leader in this sector.

Thank you very much.

Press release: Latest government large scale fire safety test results published

The fourth in the government's series of large-scale fire safety tests, that will allow experts to better understand how different types of cladding panels behave with different types of insulation in a fire, has been completed by the Building Research Establishment (BRE).

This fourth test was of a wall cladding system consisting of Aluminium Composite Material (ACM) cladding with a fire resistant polyethylene filler

(category 2 in screening tests) and stone wool insulation (a form of mineral wool). This combination of materials has passed the test.

The government's Expert Panel advise that the results show that this combination of materials can be compliant with current Building Regulations when installed and maintained properly. It could therefore offer a possible solution for some buildings with other cladding systems which have been identified as a hazard.

However the Expert Panel note that cladding and insulation materials can vary between manufacturers and can have different calorific values. The way materials have been fitted and maintained can also affect the safety of the cladding system.

Therefore the clear advice from the Expert Panel is that building owners need to continue to take professional advice as to whether any remedial work is necessary to ensure the safety of their building. The test results published today (11 August 2017) will help inform this work but they must also take into account the specific circumstances of their building.

13 buildings over 18 metres tall in England are known to have this combination of ACM with a fire resistant polyethylene filler (category 2) and stone wool insulation. Following initial screening tests, government issued advice to building owners detailing immediate interim safety measures that needed to be undertaken. These measures have been completed for all 13 of these buildings.

The government announced the independent review of building regulations and fire safety on 28 July 2017. This forward-looking review will examine the regulatory system around the design, construction and on-going management of buildings in relation to fire safety as well as related compliance and enforcement issues.

Results of the first 3 tests have already been published. Results of all remaining large-scale tests will be published when they are available.

Press release: Mandatory CCTV in all slaughterhouses under new animal welfare plans

CCTV will be mandatory in all slaughterhouses in England under new plans announced today (11 August 2017) by Environment Secretary Michael Gove, as he outlined a series of measures to cement the UK's position as a global leader on animal welfare.

The proposals will deliver a manifesto commitment for CCTV to be required in every slaughterhouse in England in all areas where live animals are present, with unrestricted access to footage for Official Vets – reassuring consumers that high welfare standards are being effectively enforced.

The Government has also confirmed it will raise standards for farm animals and domestic pets by modernising statutory animal welfare codes to reflect enhancements in medicines, technology and the latest research and advice from vets. The codes will remain enshrined in law and the first to be updated will cover chickens bred for meat.

Environment Secretary Michael Gove said:

> We have some of the highest animal welfare standards in the world and the actions I am setting out today will reinforce our status as a global leader.
>
> As we prepare to leave the EU, these measures provide a further demonstration to consumers around the world that our food is produced to the very highest standards.

Consultations on both proposals will be accessible online from 9am on 11 August 2017.

Under the new plans for CCTV, footage would be accessible to the Food Standards Agency's (FSA) Official Veterinarians (OVs), who monitor and enforce animal welfare standards in the slaughterhouse. The FSA has strict processes in place for the approval of slaughterhouses, and specially trained vets carry out checks to make sure the welfare of animals is protected throughout their time in the slaughterhouse. If breaches are found, a slaughterhouse can be given a welfare enforcement notice, have its staff's licences suspended or revoked, or be referred for a criminal investigation.

Welcoming the Government's plans, British Veterinary Association President Gudrun Ravetz said:

> Mandatory CCTV in all areas of slaughterhouses will provide an essential tool in fostering a culture of compassion that could help safeguard animal welfare and we are particularly pleased to see a commitment to Official Veterinarians having unrestricted access to footage, which BVA has been calling for. Vets' independence and unique qualifications help ensure that the UK will continue to have the highest standards of animal health, welfare and food safety.

Heather Hancock, Chairman of the Food Standards Agency, said:

> The Food Standards Agency takes a zero tolerance approach to any breaches of animal welfare standards in slaughterhouses. Last year,

> we concluded that it was time to make CCTV compulsory in slaughterhouses, progress on voluntary adoption having plateaued.
>
> I and the Board of the FSA warmly welcome Defra's consultation about making CCTV mandatory. We look forward to the introduction of a comprehensive requirement for using, accessing and retaining footage from CCTV in abattoirs. We see CCTV as an invaluable management tool for business owners to help with compliance with official controls and to improve animal welfare standards across the industry.

Updates to the meat chicken welfare code have been developed to reflect the most up-to-date best practice on poultry farms across the country. Welfare codes on laying hens, pigs, dogs, cats and horses are expected to be updated over the next year.

News story: Matchmaking scheme helps businesses find £4 million of finance

Over the past 9 months, 230 small businesses from beauticians to forklift truck training companies, which were rejected for loans by some of the UK's biggest banks, have gained £3.8 million from alternative lenders.

The government-backed bank referral scheme, launched in November 2016, requires 9 of the UK's biggest banks to pass on the details of small businesses they have turned down for loans to three finance platforms – Funding Xchange, Business Finance Compared and Funding Options. These platforms then share their details with alternative finance providers and go on to facilitate a conversation between the business and any provider who expresses an interest in supplying finance to them.

The Economic Secretary to the Treasury, Stephen Barclay, said:

> Small- and medium-sized businesses are the backbone of Britain's economy and it is right they have access to a wide range of sources of finance.
>
> A refusal from a big bank should not be the end of the line for a small business and, thanks to our match-making scheme they have another avenue to try for funding.
>
> Over 200 businesses from beauticians to forklift truck training firms have received the money that they need to grow and we expect this number to increase as the scheme matures.

Loans resulting from this scheme ranged from £200 to £500,000, with an average size of £16,000. A number of sectors have benefited including construction, retail, technology and science.

A fourth finance platform, Alternative Business Funding, will join the scheme from 1 November 2017 to widen further the options available to businesses. The government will continue to work with banks to embed and improve their referral processes.

Mike Cherry, National Chairman, Federation of Small Businesses, said:

> FSB championed the proposals for a mandatory bank referral scheme, to diversify the lending market and boost the provision of alternative finance to those turned down by the main traditional banks. We welcome that Government has delivered the three platforms and congratulate the scores of firms that have benefited in the scheme's early stages. To provide further economic benefit across the UK the scheme must now scale-up, with more referrals and more businesses successfully securing finance as a result.

Keith Morgan, CEO of the British Business Bank, said:

> As highlighted by our recent 2017 Small Business Finance Markets report, the most common response from smaller businesses when they do not get the full amount of finance applied for is to give up or cancel their plans. This can mean businesses missing potential expansion opportunities, with a knock-on effect on UK economic growth. It is therefore heartening to see the positive start made by the bank referral scheme.

Research shows that 71% of businesses seeking finance only ask one lender and, if rejected for finance, many simply give up on investment rather than seek alternative options. In 2016 220,000 small and medium sized business sought a loan or overdraft, 25% of these were initially declined by their bank and only 7% of those declined were referred to other sources of help.