Cheaper drug could release more than GBP 13.5 million a year within the next five years for other services

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Doctors in the north east of England face legal action from two of the world's largest pharmaceutical companies for offering patients with a serious eye condition the choice of a safe, effective but much cheaper drug, reports *The BMJ* today.

Prescribing the cheaper drug could save the region's NHS up to £13.5m a year within the next five years. But drug companies Bayer and Novartis are threatening legal action, claiming it would breach a patient's legal right to an approved drug.

Some estimates suggest that a switch to bevacizumab for relevant eye conditions could save the NHS around £500 million per year.

Lucentis (ranibizumab) and aflibercept (Eylea) are licensed to treat wet age related macular degeneration (AMD) - a leading cause of blindness among older patients. Avastin (bevacizumab), is not licensed for wet AMD, but several publicly funded trials have shown that it is as safe and effective as aflibercept and ranibizumab.

Patients in the region will be told they could have ranibizumab and aflibercept if they would rather. They will also be told about how much cheaper bevacizumab is and the cost savings to the NHS.

However, both Bayer and Novartis spokespeople say that using

unlicensed medicines instead of a licensed NICE approved option undermines the regulatory framework and NHS constitution. "Bayer feels it has to act to challenge the decision taken by these CCGs," a Bayer spokesperson said.

Allowing doctors to offer bevacizumab as the preferred treatment could save hundreds of millions of pounds every year that the NHS could re-invest in other frontline services. But prescribing an off-label drug goes against GMC prescribing guidance.

It is this guidance that doctors say has deterred them from prescribing bevacizumab despite the evidence of its efficacy and safety, and the financial strain on the NHS. Andrew Lotery, Professor of ophthalmology at Southampton University told The BMJ: "It's purely the regulatory framework that is stopping bevacizumab's widespread use in the NHS."

Back in 2015, The BMJ questioned the interpretation of European law that led to the GMC's stance. The advice appeared at odds with clinical practice in other European countries.

In 2014, Roche and Novartis were fined €180m by the European Court of Justice for allegedly colluding to prevent the use of bevacizumab by exaggerating the risks of using it to treat wet AMD and portraying ranibizumab as safer. The companies have challenged this at the European Court of Justice (ECJ).

But a recent opinion by a senior adviser to the ECJ suggests that off label drugs can be considered in place of licensed drugs for various reasons and this includes their price.

Faced with this news, the GMC said it is "sympathetic to the frustrations of doctors and organisations seeking to use resources effectively".

Assistant Director of Standards and Ethics Mary Agnew said: "We hope that some sort of licensing solution for drugs such as Avastin may be forthcoming, or alternatively that the situation is clarified in the courts to give doctors more assurance about when they can prescribe this drug safely and within the law."

Professor Lotery says his eye unit is experiencing "extreme pressure" due to a lack of capacity, as are other hospital eye services across the country. "Savings made by using bevacizumab should be reinvested into the hospital eye service to build capacity to deliver sight saving treatment for age-related macular degeneration," he argues.

In an accompanying commentary, Dr David Hambleton, Chief Officer at South Tyneside Clinical Commissioning Group (CCG), says offering patients the choice of bevacizumab could save the region's NHS up to £13.5m a year within the next five years, helping it to fund important medical treatment in other areas.

He argues that pharmaceutical companies "should not dictate which drugs are available to NHS patients. The choice between three clinically effective drugs should be one for NHS clinicians and patients to make together."

He is confident that EU drug marketing laws do not allow drug companies to restrict the ability of the NHS to offer patients a choice, and that the CCGs are acting lawfully.

"Clinical safety and effectiveness are paramount but, as the legal guardians of finite NHS resources, we commissioners also have a duty to act efficiently, effectively and economically," he writes. "Difficult choices are having to be made about the NHS to ensure safety and sustainability - this is one choice that is morally and ethically clear."

More information: Deborah Cohen. Are the odds shifting against pharma in the fight for cheaper treatment for macular degeneration?, *BMJ* (2017). DOI: 10.1136/bmj.j5016