

**WRITTEN STATEMENT**

**BY**

**THE WELSH GOVERNMENT**

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| **TITLE** | **Use of bevacizumab (Avastin®) for treatment of wet age-related macular degeneration** |
| **DATE** | **03 October 2018** |
| **BY** | **Vaughan Gething, Cabinet Secretary for Health and Social Services** |

I welcome the decision made by the High Court on Friday 21 September, dismissing an application for judicial review by two pharmaceutical companies to challenge the policy of 12 Clinical Commissioning Groups in England which offered bevacizumab (Avastin®)as an option for the routine treatment of wet age-related macular degeneration (wet AMD).

The High Court’s decision confirms NHS clinicians should be able to offer patients a choice between licensed medicines and unlicensed medicines for the treatment of wet AMD where there is clinical evidence of equivalent safety and efficacy.

Earlier this year, the National Institute for Health and Care Excellence (NICE) issued guidance that unlicensed bevacizumab is of equivalent clinical effectiveness and safety to the licensed medicines used in the treatment of wet AMD. The use of bevacizumab for this indication is highly cost effective.

The Medicines and Healthcare Products Regulatory Agency’s (MHRA’s) guidance on the prescribing of unlicensed medicines is that where a UK licensed product is available which can meet the clinical need of a patient; it should be used instead of an unlicensed product. The High Court ruling confirms medicines regulators do not have exclusive competence to decide whether a drug or other medicinal product is safe, clinically effective or cost-effective: The NHS is legally competent to make its own decisions on these matters.

Ultimately it will be for health boards to consider how they respond to the High Court ruling. The ruling sets out some of the practical challenges which will need to be addressed before health boards can offer bevacizumab as a routine treatment option. Health boards are giving these matters their active consideration.

The Welsh Government takes access to medicines very seriously; in 2015 we invested £16m to ensure treatment for wet AMD was available promptly and consistently across Wales. Our £80m New Treatment Fund is ensuring medicines recommended by NICE and the All Wales Medicines Strategy Group are available to patients in Wales faster than ever before. I am very supportive of the important role the pharmaceutical industry has in developing innovative medicines to market; however, I am pleased with the finding of this case that the pharmaceutical industry cannot have unbounded power to decide which medicines are made available for which purposes.

We currently spend over £21m annually on licensed medicines for the treatment of wet AMD. If significant numbers of patients were treated with bevacizumab it would result in significant savings for the NHS in Wales which could be reinvested in treating more patients.

The High Court’s decision materially changes the market for wet AMD treatment. This presents an opportunity for the manufacturers of licensed treatments to urgently consider how they will engage constructively with NHS Wales to ensure that we are receiving value for the significant public investment made in the treatment of wet AMD. I strongly encourage them to do so.

Loss of sight is devastating and we will do everything we can to prevent eye disease and ensure cost effective medicine is available to treat patients in a timely manner.