Part 6: The consequences of the judgment

The immediate position is that the pharmaceutical companies would be entitled to seek permission to appeal this judgment to the Supreme Court. It remains to be seen whether, if such an application is made, the Supreme Court would be prepared to grant permission. However, NHS bodies are entitled to proceed on the basis that the law has been correctly set out by the decision of the Court of Appeal unless and until any decision of the Supreme Court reaches a different conclusion.

Even then, by that stage, given that NICE has come out firmly in favour of using Avastin for wet AMD patients and the UK is likely to be free of EU restrictions by the date of any Supreme Court judgment. Subject to any arrangements in the future EU-UK relationship agreement, it would be entirely possible for the government to pass Regulations in order to allow the NHS to continue to treat wet AMD patients using Avastin - just as they are regularly treated in this way in the United States, in many other countries in the world and in other EU countries.

The position of the Secretary of State in the Court of Appeal was that NHS bodies ought to be able to use Avastin to treat wet AMD patients, subject to the introduction of a prior prescription system. Accordingly, even if the pharmaceutical companies were to appeal this decision to the Supreme Court, and depending on the precise terms of any ruling, there must be a strong case that the government can be expected to legislate to ensure that this practice continues.

That should give some assurance to NHS bodies to allow them to move quickly to adopt policies along the lines followed by the CCGs in the North East of England. NHS bodies that need specific advice are invited to contact Ben Connor at Landmark Chambers who will be able to refer them to specialist counsel who can provide detailed advice on these issues.

At present, a prior prescription system is needed before Avastin can be lawfully compounded in an NHS pharmacy. This requirement applies if the drug is compounded in a

hospital pharmacy for use within the hospital or is compounded in a different hospital pharmacy which is preparing compounded Avastin on a large scale.

Although the details will need to be worked out in each individual case, this should not present an insuperable barrier because this drug is provided on a repeated basis - often at monthly intervals - to a stable cohort of patients. Accordingly, when the ophthalmologist first discusses the choice of drug with the patient, if the patient chooses to be treated with Avastin it will be necessary for the ophthalmologist to sign a prescription for the patient and then communicate the existence of that prescription to the compounder.

Hospitals are likely to have an established cohort of wet AMD patients who are receiving treatment at regular intervals, where prescriptions are written for the future treatment of these patients. The compounding pharmacy does not need to see the prescriptions - it just needs to be assured that the prescriptions are in existence prior to carrying out the process of compounding and then supplying the drug to the hospital. Even though most prescriptions are electronic, this should not present significant difficulties in practice once a proper system has been set up.

There are some difficult questions about the extent to which any savings from this policy should accrue to the benefit of the CCG or should be passed on to the Trust, whether there should be a risk share agreement under which benefits are shared between the CCG and the trust. As most NHS organisations are moving towards integration within an Integrated Care System, these issues are likely to be less contentious than they would have been when commissioners and providers were working at arms length in the managed competitive market created by the 2012 Act.

This judgment presents both a substantial opportunity and a substantial challenge for the relatively few NHS pharmacies that are set up to compound Avastin at an industrial scale. It appears inevitable that there will be substantially increased demand for compounded Avastin from ophthalmologists throughout the NHS who seek to take advantage of the opportunities provided by this judgment. However, the practical challenges of scaling up

production arrangements are not to be underestimated. It may well be that the focus of attention on the present pandemic means that implementation of these changes is delayed until the NHS is through the present crisis. That may well give NHS pharmacies the opportunity to plan to meet demand.

The clinical evidence base supporting the use of Avastin off label for wet AMD patients was substantial. However, this situation is not unique. There are a number of other medical conditions where there are both licensed and unlicensed treatments available, often with very significant price differences between the licensed and unlicensed treatments. This judgment emphasises that the licensing conditions imposed in the marketing authorisation are solely related to the activities of those engaged in the commercial supply of drugs but do not impinge on the clinical freedom of doctors to make prescribing decisions.

There are, however, serious issues about the extent to which a doctor will act in breach of the GMC Code of Practice if a decision is made to offer an unlicensed drug where there is a licensed alternative. These are complex issues which will have to be worked through on a case-by-case basis but the general approach of the GMC has been demonstrated by its strong approval of the prescribing of Avastin for wet AMD patients in the present case. But approval was grounded in the solid clinical evidence base to support this form of prescribing, and also by the tacit support given to this approach by the NICE Guidance.

Off label prescribing in other circumstances may not have the benefit of such a solid evidence base but nonetheless may be entirely legitimate. There are also some difficult questions about the extent to which the *Apozyt* exemption can be relied upon to compound other drugs. Again, this will have to be considered on a case-by-case basis.

This judgment is likely to lead to a substantial rethink by NICE. The decisions that Lucentis and Eylea represented cost-effective interventions that the NHS should fund were predicated on the basis that it was unlawful to introduce Avastin as a comparator. That position is no longer the case and accordingly there must be serious questions as to whether the analysis which led to the Technology Appraisal Guidance which supports the use of

Lucentis and Eylea needs to be rethought. An urgent review of those TAGs appears to be called for.

When the original judgment was produced, estimates were made that the NHS might be able to save up to £500M per year by switching patients from Lucentis or Eyelea to Avastin. Whilst that may have been over estimate, it was a figure which was relied upon by the pharmaceutical companies in seeking permission to appeal. Given the enormous financial pressures on the NHS, we would suggest that this is an enormously welcome judgment which clears the way for NHS bodies to make choices about drugs based on their assessment of the clinical effectiveness and cost-effectiveness of the drug in question, unrestrained by choices made by pharmaceutical companies as to which drugs are put through the EMA process for which groups of patients.

Thus, in strategic terms, this judgment represents a significant move of decision-making power from the pharmaceutical companies to NHS bodies.

Thank you for taking the time to listen to this podcast. If you have any further queries arising out of this case please do not hesitate to contact our clerks.