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Background briefing: outcome of judicial review

Q. What is judicial review?

- A. Judicial review is a High Court procedure for challenging administrative actions. Delegated legislation may also be challenged. It allows individuals, businesses or groups to challenge in court the lawfulness of decisions taken by Ministers, Government Departments and other public bodies. These bodies include local authorities, the immigration authorities, regulatory bodies and some tribunals.

Q. What were the specific grounds for this judicial review?

- A. The grounds on which the Claimant sought to challenge the decision by NICE, to issue guidance in its present form, fall under three broad headings. First, it was said that the decision was irrational, on four different but very limited grounds. Secondly, it was said that the decision was procedurally unfair, in one specific respect. Thirdly, it was said that the decision was indirectly discriminatory against certain groups.

Q. Who has taken NICE to Court?

- A. A Japanese pharmaceutical company called Eisai, which is the licensed holder of one of the drugs NICE recommended for use in patients with moderate stage Alzheimer's. Their press releases state that they are doing this with the 'full support' of Pfizer, the company which markets the drug and is one of the world's largest pharmaceutical companies.

Q. What was the role of the Alzheimer's Society in the case?

- A. The Alzheimer's Society registered as an interested party, but it was the pharmaceutical company Eisai who took this legal action, with Pfizer in support. The Alzheimer's Society had the opportunity to contribute to the proceedings and submit evidence. The pharmaceutical company Shire Ltd have also registered as an interested party in this case and will also have the opportunity to contribute to the proceedings and submit evidence.

Q. What has the judge decided?

- A. The judge ruled in favour of NICE on five out of the six grounds brought in court, including finding:

- That NICE did appropriately take into account the benefits these drugs bring to carers.
- That NICE appropriately reflected the costs of long term care in its calculations.
- That NICE did not breach principles of procedural fairness by providing a 'read only' version of the economic model.
- That NICE was not irrational in concluding that there is no cumulative benefit to patients after six months treatment with these drugs.
- That NICE's assessment and consideration of the AD 2000 study was not irrational.

The judge ruled against NICE on one of the six grounds brought in court:

- That NICE did breach its duties under the Disability Discrimination Act and the Race Relations Act by not offering specific advice regarding people with learning disabilities and people for whom English is not their first language in its technology appraisal guidance.

Q. What is your response to today's ruling?

- A. We were challenged in court on six grounds, and the judge has rejected five of the six points made against us. It has always been our intention that people with learning disabilities or people whose first language is not English, should have equal access to these drugs in the moderate stage of Alzheimer's disease. We have reissued our guidance to the NHS to make this crystal clear.

NICE has amended and reissued this guidance. The amended guidance clarifies the steps healthcare professionals should take when assessing whether Alzheimer's disease is of moderate severity and highlights that clinicians should be mindful of the need to secure equality of access to treatment.

The amendments include new text that specifically addresses assessments, using the Mini Mental State Examination (MMSE) for patients:

- where the MMSE is not, or is not by itself, a clinically appropriate tool for assessing the severity of that patient's dementia because of the patient's learning or other disabilities (for example, sensory impairments) or linguistic or other communication difficulties

or

- where it is not possible to apply the MMSE in a language in which the patient is sufficiently fluent for it to be an appropriate tool for assessing the severity of dementia, or there are similarly exceptional reasons why use of the MMSE, or use of the MMSE by itself, would be an inappropriate tool for assessing the severity of dementia in that individual patient's case.

The amended guidance has been published on our website [link to TA guidance page] on Friday 7 September and will have force from that date. It will be distributed to the NHS in paper form as part of our standard monthly mailing on Wednesday 26 September.

We appreciate that Alzheimer's is a devastating illness for patients and their carers, and we hope that the advice we issued last year on the broader support that should be provided for people with Alzheimer's disease and those who care for them will make a real difference for patients and their families.

Q. Does this ruling mean that more people with Alzheimer's disease will receive treatment with these drugs?

A. No. Our guidance stands, and the drugs continue to be recommended only for people with moderate Alzheimer's disease. It has always been our intention that people who have learning disabilities, or people whose first language is not English, should have equal access to these drugs in the moderate stage of the disease. We will reissue our guidance to the NHS to make this crystal clear.

Q. How do you respond to the judge's criticism of NICE compliance with the Disabilities Discrimination Act and the Race Relations Acts?

A. We were aware of the law and we thought we were complying with it, but it is clear that we did not do enough. We will reissue our guidance to make crystal clear how people with Alzheimer's disease who have learning disabilities, or people whose first language is not English, should be supported. The judgment will also help us to make sure that we are compliant with our duties and can do the right thing in future.

Q. Can clinicians prescribe these drugs to patients outside your recommendations if they disagree with your recommendations?

A: No. Health professionals should not prescribe these drugs to those in the mild stages of the disease just because they do not agree with the guidance. NICE recommends the drugs only for the treatment of those whose Alzheimer's disease is assessed as being moderate.

Q. Does this have wider implications for your processes?

A. We were challenged in court on six grounds, and the judge has rejected five of the six points made against us. This ruling strengthens NICE by endorsing our fundamental approach to evaluating drugs in one of the most controversial decisions we have ever been asked to make.

Q. Is this the first time NICE has faced a judicial review?

A. Yes

Q. Does this ruling have implications for existing NICE guidance or guidance currently being developed?

A. No. The issuing of judicial review proceedings in this case is a legal challenge against a specific part of the process NICE used to assess the effectiveness of drugs to treat Alzheimer's disease. As such, it will not create any wide-ranging precedent, nor force NICE to reconsider any decisions relating to other drugs or procedures.

Q. Will this increase the cost to the NHS of prescribing drugs for Alzheimer's disease?

- A. No. It has always been our intention that people who have learning disabilities, or people whose first language is not English, should have equal access to these drugs in the moderate stage of the disease. We had factored atypical group into the costing advice we provide for the NHS, and these estimates will not change in light of the courts ruling.