

WEDNESDAY 31ST MARCH 2010

**IN THE COURT OF APPEAL**

016425

ON APPEAL FROM THE HIGH COURT OF JUSTICE  
QUEEN'S BENCH DIVISION  
ADMINISTRATIVE COURT

CO24692008

**BEFORE** LORD JUSTICE PILL  
LADY JUSTICE SMITH  
And LORD JUSTICE WILSON

**B E T W E E N**

THE QUEEN ON THE APPLICATION OF SERVIER LABORATORIES LIMITED  
CLAIMANT/APPELLANT

- and -

THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE  
DEFENDANT/RESPONDENT

- and -

THE NATIONAL OSTEOPOROSIS SOCIETY  
INTERESTED PARTY

**ON READING** the Appellant's Notice sealed on the 15th April 2009 filed on behalf of the Claimant on appeal from the order of The Honourable Mr Justice Holman dated 20th March 2009

**AND UPON CONSIDERING** written submissions and evidence filed by the parties on 30 March 2010

**AND ON HEARING** Mr Clive Lewis QC and Mr Martin Chamberlain for the Appellant and Mr Michael Beloff QC and Mr Daniel Stilitz for the Respondent

**IT IS ORDERED** that:

- 1) The appeal be allowed. The Respondent's decision to issue Final Appraisal Determinations dated July 2008 and amended in December 2009, and the Technology Appraisal Guidance dated October 2008 and amended in January 2010 (TA 160 and TA 161) relating to the primary and secondary prevention of osteoporotic fragility fractures in post-menopausal women were unlawful insofar as the Respondent failed to give reasons for rejecting the Appellant's evidence as to the efficacy of



Her Majesty's  
Court of Appeal  
01 APR 2010

COURT 71  
Appeal No.

C1/2009/0805

Amended by order of  
Lady Justice Smith as  
underlined in red this  
22nd day of April 2010



strontium ranelate in reducing hip fractures. The Respondent will make a fresh decision and issue fresh guidance in respect of S.R. ~~within 3 months of today's date.~~ in accordance with an agreement set out in correspondence between the parties.

- 2) The Respondent shall pay to the Appellant:
  - a) the Appellant's costs of the appeal, save for 50% of the costs of the application for permission to appeal; and
  - b) 60% of the Appellant's costs of the claim in the Administrative Court such costs to be the subject of a detailed assessment on the standard basis if not agreed.
- 3) The Respondent shall within 21 days of the date of this Order pay to the Claimant the sum of £50,000 by way of payment on account of the costs set out in paragraph 2 above.
- 4) Permission to appeal to the Supreme Court of the United Kingdom be refused.
- 5) A memorandum of understanding is annexed to this order, the terms of which are to be carried out forthwith



*By the Court*

---

## MEMORANDUM OF UNDERSTANDING

---

The parties have agreed the following Memorandum of Understanding to accompany the Order of the Court herein. This sets out the scope of a communication that the Respondent will send to the relevant National Health Service bodies described below. The communication will clarify the status of the guidance issued by the Respondent (on the primary and secondary prevention of fractures in postmenopausal osteoporotic women) in relation to strontium ranelate until a fresh decision on the guidance is finalised.

### **Communication to NHS bodies**

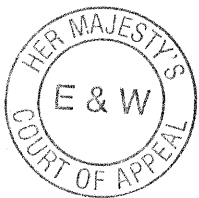
The Respondent will communicate with all NHS bodies which will have received the relevant guidance:

- “(a) NICE’s decision to issue Final Appraisal Determinations and Guidance relating to the primary and secondary prevention of osteoporotic fragility fractures in post-menopausal women have been declared by the Court of Appeal to be unlawful insofar as NICE has failed to give adequate reasons for rejecting Servier’s evidence as to the efficacy of strontium ranelate in reducing hip fractures.
- (b) Servier contends that NICE should have accepted an estimate of efficacy for strontium ranelate in reducing hip fractures from a post hoc study that was accepted by the European Medicines Agency in support of the grant of a marketing authorisation for strontium ranelate in reducing the risk of hip fracture. NICE has not accepted the level of efficacy from the post hoc study, which is substantially higher than the figure that was accepted by NICE (a 36% decrease in risk of hip fracture versus the 15% decrease that was accepted by NICE).
- (c) NICE has been ordered by the Court to reach a fresh decision on the efficacy, and therefore cost-effectiveness, of strontium ranelate.
- (d) In these circumstances, NHS commissioning bodies should make their own local arrangements as to the circumstances in which strontium ranelate can be prescribed in addition to the positive recommendation in the current Guidance.
- (e) The Guidance on the use of strontium ranelate is being reconsidered and will be reissued in due course.”

The Respondent will also provide to the Appellant a list of all the NHS bodies to whom the communication is sent.

### **Fresh decision**

The parties have agreed in correspondence a detailed timetable and procedure which will be followed in the reappraisal of strontium ranelate.



**WEDNESDAY 31ST MARCH 2010  
IN THE COURT OF APPEAL**

ON APPEAL FROM THE  
THE HIGH COURT OF JUSTICE  
QUEEN'S BENCH DIVISION  
ADMINISTRATIVE COURT

THE QUEEN ON THE APPLICATION OF SERVIER  
LABORATORIES LIMITED

- and -

THE NATIONAL INSTITUTE FOR HEALTH AND  
CLINICAL EXCELLENCE

-and-

THE NATIONAL OSTEOPOROSIS SOCIETY

ORDER

Copies to:

Queen's Bench Division - Administrative Court  
Room C317  
Royal Courts of Justice  
The Strand  
London WC2A 2LL

Messrs Beachcroft  
Dx 45  
London  
Ref: SH/JZE/NAT120-0516950

Messrs Bristows  
Dx 269  
Chancery Lane  
Ref: 393/MIM/09360 0072

The National Osteoporosis Society  
Camerton  
Bath  
BA2 0PJ  
Ref: NICK RIJKE

\*

---

\* This order was drawn by Ms A Lehane (Associate) to whom all enquiries regarding this order should be made. When communicating with the Court please address correspondence to Ms A Lehane, Civil Appeals Office, Room E307, Royal Courts of Justice, Strand, London WC2A 2LL (DX 44450 Strand) and quote the Court of Appeal reference number. The Associate's telephone number is 020 7947 6879