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# Pharmaceutical subsidisation and judicial review of the National Institute for Clinical Excellence

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**Abstract** This paper outlines the nature and rules of the National Institute for Clinical Excellence (NICE) and, in the context of pharmaceuticals, assesses whether NICE is subject to judicial review, whether its members can be cross-examined, whether fresh evidence can be adduced at review hearings, the courts' likely approach to challenges to NICE's exercise of discretion on matters of substance and some aspects of the consultation obligations to which NICE is subject.

**Keywords:** National Institute for Clinical Excellence, appraisal process, appeal, judicial review, cross-examination, fresh evidence, substantive review, procedural review

## Introduction

The National Institute for Clinical Excellence was established in April 1999 to assess the safety, quality, efficacy and cost-effectiveness of, among other things, new and existing pharmaceuticals referred to it for appraisal and to advise the Health Secretary as to which ones should be made available at National Health Service (NHS) expense. Its decisions may preclude Jane Public from obtaining, care of the state, the pharmaceutical she needs, prefers or would otherwise be prescribed. Those decisions may also have a considerable economic impact on pharmaceutical suppliers. Suppliers faced with adverse 'guidance decisions' of NICE are already appealing NICE's decisions (pursuant to NICE's published guidelines). Before long they may appeal for judicial review of those decisions.

Guidance as to the judicial approach likely to be followed in Britain can be taken from decisions from other common law jurisdictions where the kinds of issues likely to be raised have already been considered.<sup>1</sup>

## The nature and rules of NICE

NICE was set up as a Special Health Authority to 'perform such functions in connection with the promotion of clinical excellence and of the effective use of available resources as the Secretary of State may direct'.<sup>2</sup> It appraises individual health interventions to promote the appropriate use of those that offer good value to patients and to discourage the use of those that do not. For more detailed information on the constitution of NICE and its guidelines (summarised below) readers are referred to NICE's web site.<sup>3</sup>

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### Referrals of interventions to NICE

The Department of Health is primarily responsible for determining which interventions should be referred to NICE based on one or more of the following criteria:<sup>4</sup>

- Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
- Is the technology likely to result in a significant impact on other health-related government policies (eg reduction in health inequalities)?
- Is the technology likely to have a significant impact on NHS resources (financial or other) if given to all patients for whom it is indicated?
- Is NICE likely to be able to add value by issuing national guidance?

Both new and existing interventions may be referred. The NHS Executive has said the Department will need to ensure that referrals for NICE appraisal do not inadvertently give a competitive advantage to one product over another<sup>5</sup> and that the selection process must be demonstrably even-handed.<sup>6</sup> According to NICE's draft 'Guide to the Technology Appraisal Process' issued for consultation on 8<sup>th</sup> December 2000, before deciding whether to refer a particular intervention to NICE, the Department of Health and National Assembly for Wales consult with, among others, manufacturers and sponsors of the intervention in question.

### NICE's task and considerations to be taken into account

NICE's task is to assess the evidence of all the clinical and other health-related benefits of an intervention, to estimate the associated costs, and to reach a judgment on whether on balance the intervention can be recommended as a cost-effective use of NHS resources (in general or for specific indications, subgroups, etc.).<sup>7</sup> In reaching this judgment, NICE will have regard to

those factors listed in the Secretary of State's Directions, namely:<sup>8</sup>

- the Secretary of State's and the National Assembly of Wales' broad clinical priorities (as set out for instance in National Priorities Guidance and in National Service Frameworks, or any specific guidance on individual referrals);
- the degree of clinical need of the patients with the condition under consideration;
- the broad balance of benefits and costs;
- any guidance from the Secretary of State on the resources likely to be available and on such other matters as he may think fit; and
- the effective use of available resources.

According to the draft 'Guide to the Technology Appraisal Process', a further factor NICE will take into account in its appraisal is "the wish to be sympathetic to the longer-term interests of the NHS in encouraging innovation of good value to patients".

Having appraised a given intervention NICE produces guidance on the appropriate use of the intervention alongside current best practice.

### The appraisal process

As at the submission date for this paper, the nature and content of submissions to be made when a new or existing technology (including a pharmaceutical product) is being appraised and the process to be followed by NICE were set out in NICE's 'Appraisal of New and Existing Technologies: Interim Guidance for Manufacturers and Sponsors'.<sup>9</sup> The key procedural stages were as follows:

- Relevant manufacturer(s) will be invited to submit evidence of clinical and cost effectiveness, for appraisal.
- Appraisal submissions, in some cases together with additional published evidence, will be assessed by NICE's secretariat or, on its behalf, by nominated external individuals or groups.
- An Evaluation Report will then be prepared for consideration by the

Appraisals Committee, together with a Draft Provisional Appraisal Determination.

- The appraisal submissions and the Evaluation Report will then be considered by NICE's Appraisals Committee. The Committee will approve or amend the Draft Provisional Appraisal Determination.
- The Appraisal Committee's provisional advice – the Provisional Appraisal Determination – will then be made available to relevant manufacturer(s), professional and patient organisations and the Department of Health and National Assembly for Wales, for comment. A copy of the Evaluation Report will also be made available once commercially confidential material has been removed.
- The Appraisal Committee will then review its provisional advice in the light of representations received and submit its Final Appraisal Report/Determination to NICE's Appraisal Executive Board.
- The Board will consider the Determination and amend the proposed guidance to the NHS if and as it sees fit. It will then forward the Determination to relevant manufacturer(s) or sponsor(s) who have 10 working days to decide whether to make an appeal to the Board.<sup>10</sup> At this stage the Determination and proposed guidance are confidential. (In November 2000 the NICE Board voted to remove this confidentiality requirement. The decision will probably be implemented in early 2001.)
- If there is no appeal, NICE's guidance will be issued to the NHS.

At the time of writing NICE was consulting on draft 'Revised Guidelines for Manufacturers and Sponsors of Technologies Making Submissions to the Institute'. These draft 'Revised Guidelines' contain considerably more detail on the expected content of submissions. At the same time, NICE was also consulting on the new draft 'Guide to the Technology Appraisal Process' referred to above. It will probably be finalised in February 2001 and

will become the key document setting out suppliers' procedural rights.

## Amenability of NICE to judicial review

### NICE as an advisory body

In other jurisdictions decisions concerning the subsidisation of pharmaceuticals have attracted the courts' supervisory review jurisdiction. They involve the allocation of substantial public funds, affect patients' welfare and suppliers' commercial activities and are often traceable to a statutory empowering environment. They are, therefore, profoundly public in nature and effect.<sup>11</sup>

NICE is a creature of statute and its recommendations are likewise profoundly public in nature and effect. The only barrier NICE may seek to erect to its amenability to review is the fact that, instead of making decisions that are binding upon their recipients, it provides recommendations and guidance to the NHS. In the author's view such an argument would not succeed and overseas authority that might be enlisted to support it would be distinguishable.<sup>12</sup>

In practical terms, NICE is a decision maker. It governs the process and makes decisions as to whether medicines it is asked to appraise should be, or should not be (as opposed to are not), available at NHS expense. Moreover, it is under a statutory duty to 'make reports to the Secretary of State in such manner and at such time as the Secretary of State may direct' and to 'furnish to the Secretary of State such information as he may from time to time require'.<sup>13</sup> NICE itself recognises that Technology Appraisals provide patients, health professionals and health service managers with a single, *authoritative source of advice* on new and existing health technologies. One can reasonably expect that that advice will normally be followed. Analogous authority exists to support the view that, in these circumstances, the 'guidance decisions' of NICE would be amenable to review.<sup>14</sup>

### Relevance of the appeal right

Appeal rights, if comprehensive, can in rare cases exclude judicial review. However, in the author's view it would be difficult if not impossible to argue that the appeal mechanism afforded by NICE's rules is exclusive, particularly given that:

- the rules are non-statutory;
- the appeal panel is not composed of legally qualified decision makers;
- the appeals procedure is inquisitorial; and
- the Secretary of State has the power to terminate the tenure of a 'non-officer member' forthwith upon written notice if the Secretary of State is of the opinion that it is not in the interests of the Institute or the health service that the non-officer member should continue to hold that office.<sup>15</sup>

For a court to hold otherwise may be contrary to the right to a fair trial in the Human Rights Act 1998 (section 6 and article 6.1 of the Convention).<sup>16</sup>

At the same time, failure to make an appeal may, depending on the facts, cause the Court to decline permission to apply for judicial review, influence its discretion to grant relief if a ground of review is established or influence its decision on the award of costs.<sup>17</sup> This is particularly likely to be so in the present context given that the grounds of appeal are similar to those available in judicial review.<sup>18</sup> It is also noteworthy that the draft 'Revised Guidelines' state expressly that the processes of consultation and appeal are integral to the preparation of the Institute's guidance. If a failure to appeal is established to have been deliberate, the applicant for review risks its application being castigated as an abuse of process.<sup>19</sup> However, the courts are likely to be more lenient where difficult and/or novel questions of law are involved.<sup>20</sup>

### Interlocutory questions

#### Cross-examination

Evidence in judicial review proceedings is usually given by affidavit and cross-

examination of witnesses on their affidavits is not permitted as of right.<sup>21</sup> Leave to cross-examine must be sought. In practice cross-examination in judicial review is rare.<sup>22</sup> Nevertheless, an affected pharmaceutical supplier may wish to apply to cross-examine Appraisal Committee or Board members in the belief there is a better chance of establishing its case through cross-examination. The difficulties suppliers may encounter are evident in New Zealand authority.

In 1997 the New Zealand High Court and Court of Appeal were faced with an application by Roussel Uclaf Australia to cross-examine members of the Pharmaceutical Management Agency Limited (PHARMAC) and the Pharmacology and Therapeutics Advisory Committee (PTAC) in relation to PHARMAC's therapeutic subgrouping of Rulide with the erythromycin antibiotics. (PHARMAC is the body that decides, among other things, which pharmaceuticals should be subsidised, while PTAC is its independent expert advisory committee.) In the High Court Gallen J disallowed the application. His Honour's reasoning is instructive:<sup>23</sup>

... the comments in [*O'Reilly v Mackman* [1983] 2 AC 237] indicate the undesirability of effectively converting review proceedings not only into an appeal, but into a consideration by the Court of the very matters which some other person or body has been appointed by Parliament to decide.

... This case is in some respects a good example of the reasons why such cross-examination would not normally be considered appropriate. Before bodies of this kind as indeed before Courts, it is common now for massive amounts of material to be produced, referred to and argued upon and it is clear that this case is no exception. Indeed, it would hardly have been possible to avoid placing very substantive quantities of material before Pharmac before the decision, the subject of this application, was made, but the very volume of the material gives rise to difficulties. It would be quite impossible for a decision maker to refer to all material which is placed before the decision maker and there are considerable risks in allowing the decision

processes to be investigated in the way in which a cross-examination is likely to lead.

The Judge was also troubled by the fact that the decision was one of a Board with a number of interacting members, none of whose views alone would necessarily be representative of the group decision. Roussel Uclaf's appeal against this decision was dismissed.<sup>24</sup>

### Fresh evidence

After NICE has made a decision with which a supplier disagrees, new scientific studies and other information on the efficacy, side-effects and the like of the subject pharmaceutical may come to light. The supplier may wish to place such substantive material before the court to support its case and hence it may either seek permission from the court to do so or simply include such material in its written evidence. NICE may well object to either approach.<sup>25</sup>

In judicial review proceedings the purpose of evidence is to establish a breach of duty or the invalidity of a decision primarily on procedural grounds and not to establish that a public body's actions are disagreeable or unmeritorious.<sup>26</sup> For this reason the courts are usually unwilling to admit fresh or post-decision evidence for the purpose of re-opening an investigation of the factual matrix on which a decision was made. To do so would turn the review process into an appeal. In pharmaceutical subsidisation and licensing litigation the courts have so held in *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Limited*,<sup>27</sup> *Upjohn Ltd v Licensing Authority established under Medicines Act 1968*<sup>28</sup> and *Pfizer Pty Ltd v Birkett*.<sup>29</sup>

It should be noted, however, that, consistent with the nature of review, there are exceptions to the rule against admission of fresh evidence. The exceptions fashioned by the courts address the jurisdiction of the decision maker to act and the primarily procedural validity of the decision-maker's decision.<sup>30</sup> The admission of fresh evidence may, in rare cases, be appropriate. And the position in review proceedings needs to be

distinguished from the position under NICE's rules as the 'Interim Guidelines' state that if, at the appeal stage, manufacturers or sponsors submit new data then the appeal panel will normally refer it to the Appraisal Committee and adjourn the appeal hearing.

### Substantive review

While judicial review is primarily concerned with the process prior to and by which an impugned decision was made, today it would be facile to pretend the Courts do not also, in appropriate cases, undertake a review that is more substantive in nature (where, for example, there has been an unjustifiable breach of an unequivocal promise or a flagrant breach of human rights).<sup>31</sup> However, in the pharmaceutical sphere, the courts are willing to acknowledge that certain substantive issues are properly considered non-justiciable and otherwise to exercise restraint when asked to determine issues striking at the regulator's exercise of discretion.

The quintessential example of this authority is *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd*,<sup>32</sup> the interlocutory proceedings in which are referred to above. Although at first instance Roussel succeeded on one of some 28 heads of challenge (overturned on appeal), Galloway J made a number of comments on the need for judicial restraint when considering applications for review of PHARMAC's decisions. His Honour noted that, in case after case, the courts have repeated the view that it is inappropriate for the courts to make decisions that are properly reposed in those who have the expertise to make them. He said:<sup>33</sup>

... when looked at overall the whole exercise [by Roussel] amounts to an attempt to show that the decision made by [PHARMAC] was wrong. ... The decisions with regard to the provision of medicines are very frequently likely to be complex and difficult involving the weighing up of one good against another. It has already been pointed out in cases of this kind that the responsibilities imposed upon the decision maker can sometimes be

described as anguishing. They are also decisions which can only be made by persons who are technically qualified to make them on the basis of information which will itself be coloured as it is gathered, by persons of experience in the field under consideration. Nor are decisions of this kind likely often to be clearcut. Comparisons which need to be made are not always between identical substances. They not infrequently involve value judgments and judgments are inevitably made on the basis of unexpressed experience.

Gallen J noted that PHARMAC's Board members were not in the same position as busy Ministers of the Crown who may be heavily dependent on investigations carried out and reports made by departmental officials.<sup>34</sup> He also both noted and objected to Roussel's attempts to criticise the factual basis for PHARMAC's decision:<sup>35</sup>

As counsel for the respondents stressed, what Roussel seeks to do in this case is to revisit the decisionmaking process by a piecemeal consideration of the material upon which it rests. Not only is the correctness of the criticism on which Roussel relies the subject of dispute, but an approach of that kind in circumstances such as these effectively requires the Court to revisit the myriad decisions which preceded the decision itself. It is asked not only to make a decision which is reposed in an expert body specifically required to make it, but to do so without the advantages of technical knowledge and experience which the decisionmakers at each level in that process brought to bear on the decision in this case.

Decisions of the kind at present under consideration will rarely be black and white. They involve research, which must inevitably be to some extent selective. They involve comparisons where similarities will often be a matter of degree and they involve value judgments, some of the bases for which will be subsumed in the expertise of the persons required to make the decision. It is quite inappropriate in such cases for the decisions to be analysed on a factual basis and an endeavour made to show that in some one or more respects, aspects could be the subject of criticism.

The Court of Appeal made a number of comments regarding PHARMAC's decision-

making processes and the judicial deference afforded to its decision making, many of which may be relevant to challenges to the 'guidance decisions' of NICE and which may therefore need to be considered.<sup>36</sup> For example, the court said that PHARMAC must be afforded a margin of appreciation in the exercise of its functions and that the weight to be given to the criteria in its operating policies and procedures is a matter for the Board of PHARMAC.

In *Glaxo NZ Ltd v Attorney-General*, a case concerning a subsidy reduction for Zantac, the same deference was shown to Ministerial decisions under the former drug tariff regime operating in New Zealand prior to PHARMAC's inception.<sup>37</sup> In Canada, similar statements of restraint were made in *Re Ayerst, McKenna & Harrison Inc and A-G of Ontario*,<sup>38</sup> a case concerning the listing of a generic drug, CES, as being interchangeable with Premarin. And in England, the same deference was shown in relation to determinations of the Medicines Control Agency in *R v Department of Health and Social Security and Norgine Ltd, ex parte Scotia Pharmaceuticals Ltd*,<sup>39</sup> a case involving the licensing of an evening primrose oil pharmaceutical, and *R v Medicines Control Agency, ex parte Pharma Nord Ltd*,<sup>40</sup> which concerned the classification of melatonin as a medicinal product.

## Procedural review

By contrast with matters of substance and discretion, the courts are unlikely to be reluctant to correct procedural unfairness and irregularity at the hands of NICE. It is for this reason, among others, that both NICE and pharmaceutical suppliers are likely to wish to have a thorough understanding of the 'more procedural' grounds of review.

While there are many such grounds, discussion in this paper is limited to consultation principles. It may be noted, however, that authority in the context of pharmaceutical judicial review exists for many of these other grounds of review as well as for some of the more substantive grounds not specifically addressed above.

For example, challenges to the validity or scope of pharmaceutical subsidisation policies were made in *Pharmaceutical Manufacturers Association of Canada v Attorney-General for the Province of British Columbia*,<sup>41</sup> *SmithKline Beecham (NZ) Ltd v Minister of Health*,<sup>42</sup> *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd*<sup>43</sup> and *ICI Australia Operations Pty Ltd v Blewett*.<sup>44</sup> Issues of consistent treatment of similarly placed pharmaceutical suppliers were raised in the High Court, Court of Appeal and Privy Council in the *Roussel Uclaf Australia* proceedings<sup>45</sup> and in *Bristol-Myers Squibb Pharmaceuticals Pty Ltd v Minister for Human Services and Health*.<sup>46</sup> Questions of the relevance or irrelevance of considerations were considered in many of the authorities cited in this paper including, in particular, *Reckitt & Colman (New Zealand) Ltd v Pharmaceutical Management Agency Ltd* (in which concerns over the impact of 'line extensions' were held to be permissibly relevant)<sup>47</sup> and *Pfizer Pty Ltd v Birkett* (in which some of the permissibly relevant factors were the cost of overuse and inappropriate use of Viagra, the categorisation of Viagra as a 'lifestyle drug' and that Viagra did not treat a life-threatening condition).<sup>48</sup> And in *R v Secretary of State for Health, ex parte Pfizer Ltd*<sup>49</sup> advice to doctors that they should not prescribe Viagra at NHS expense was held unlawful because to state in bold terms that Viagra should not be prescribed except in undefined exceptional circumstances was tantamount to telling the recipients of the advice to follow it, thereby overriding their professional judgment and achieving what could not lawfully be achieved without an amending statutory instrument.

Although some of the consultation issues addressed below are accommodated in NICE's current guidelines, they are covered given their potential relevance to future guidelines and to other decisions taken in the area of pharmaceutical subsidisation, pricing and licensing, such as decisions regarding the Pharmaceutical Price Regulation Scheme and statutory schemes under the Health Act 1999<sup>50</sup> and decisions to 'blacklist' pharmaceuticals.<sup>51</sup>

### When is consultation required?

Whether consultation is required usually depends on whether a duty of consultation arises from past practice, a promise of or representation that there will be consultation (giving rise to a procedural legitimate expectation) or from the requirements of a statute. Consultation obligations may also arise given the nature of parties' relevant interests and the extent to which they may be affected by an adverse decision.<sup>52</sup> NICE has, in its guidelines, made many representations as to when it will consult, thereby giving rise, at least in some instances, to legitimate expectations of consultation.<sup>53</sup>

### Provision of sufficient information to consultees

The party under a duty to consult must provide consultees with a reasonable amount of information as consultees must know what is proposed before they can be expected to give their views. Reasonable information is sufficient information to enable the consulted party to tender its views.<sup>54</sup>

### How much information should be provided to advisory bodies when their views are sought?

When the views of expert advisory bodies are sought by decision makers or their staff, questions might arise as to how much information should be provided to them and as to the quality of that information. This issue was considered in *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd*.<sup>55</sup> Roussel contended that the reports provided by PHARMAC staff to PTAC and the PHARMAC Board were defective in that they were selective in the material that they contained, misstated the position with regard to historical subsidy decisions and were inadequate in drawing attention to defects in the investigatory material which had been sought by the respondents. Roussel had submitted that the members of

the PHARMAC Board were not themselves necessarily medically qualified and because of their administrative responsibilities within the organisations that they represented (the former Regional Health Authorities) were, in the same way as a Minister, bound to be dependent upon the material provided by their executive officer. Gallen J said that this approach overlooked the decision-making process contemplated in respect of pharmaceuticals. He said:<sup>56</sup>

First there is the technical committee PTAC... the members of which are technically qualified and are dealing with matters of this kind on a frequent basis. In the same way, members of the Pharmac Board also have the advantage of the experience which they bring to the assessment of matters of this kind and the knowledge gained by the fact that they are obliged to make such decisions on a regular basis.

In the end the matter may be one of degree but it is my view that before an attack of this kind could succeed with regard to decisions of the Pharmac Board or of PTAC or of the two combined, it would be necessary to show that the material provided was so defective as to in effect be deceptive.

This proposition was not disturbed on appeal. On appeal, one of Roussel's points of cross-appeal concerned a literature review that had been provided to PTAC. Roussel complained that a report on that literature review had not been provided to PTAC. The Court of Appeal was not moved by Roussel's procedural unfairness argument.<sup>57</sup>

### **Should advisory bodies' reports and views be supplied to consultees for comment?**

Where a decision maker receives and relies upon substantive advice that exceeds mere opinion, such as the advice of a medical or scientific committee, as a general rule that advice should be supplied to consultees for comment before a final view is formed and decision made.<sup>58</sup>

It does not follow, however, that every single report or piece of advice from such bodies should be provided to consultees

before a decision is made. Reports or further advice from advisory bodies may be sought in response to consultees' submissions.

Although each case should be considered on its facts it may be said, as a general proposition, that if they do not significantly add to the decision-maker's knowledge base then they need not be provided to consultees for comment.<sup>59</sup>

### **No general entitlement to the views of other consultees**

Generally one consultee is not entitled to be given the views of other consultees.<sup>60</sup>

### **Reasonable opportunity to state views**

Once sufficient information has been provided to consultees, the consultor must give those consultees a reasonable opportunity to state their views.<sup>61</sup> What is 'reasonable' will depend on the circumstances.

### **Consultees should utilise consultation opportunities**

Consultees are obliged to utilise reasonable opportunities to state their views if they wish to take part in the consultation process. A party that refrains for tactical or other reasons from putting forward its case cannot later complain.<sup>62</sup>

### **Genuine consideration of consultees' views**

Although consultation does not mean 'negotiation' or 'agreement' it clearly requires more than mere prior notification. The decision maker must genuinely consider consultees' views with an open mind.<sup>63</sup> An 'open mind' is not, however, the same as a blank mind or one 'untrammelled by any prior thought on the issues in question'.<sup>64</sup>

An example of a pharmaceutical regulator not genuinely consulting can be seen in *Glaxo New Zealand Ltd v Attorney-General*.<sup>65</sup> In that case a so-called 'proposal' to reduce the subsidy for Zantac was, in effect,



presented as a *fait accompli* to Glaxo without opportunity for genuine consultation. Subsequent exchanges were, in the words of Jeffries J, 'at best simply justification and argument for its decision already reached'.<sup>66</sup>

### Reliance on summaries of consultees' submissions

Consultation processes may produce numerous and voluminous submissions which working parties, committees or the decision-maker's staff may summarise for the decisionmaker. Although the compilation of such summaries may be a legitimate exercise, it is critical that those summaries accurately reflect the nature and breadth of individual consultees' submissions. Those who prepare such summaries should not simply dismiss or ignore aspects of submissions and thereby exclude them from the summaries simply because, in their view, those aspects carry little or no weight. That is a matter for the decision maker. Although the provision of inadequate summaries should not invalidate a decision if the decision maker actually considers the submissions received, a decision-maker's reliance upon inadequate summaries alone is likely to result in a finding of procedural unfairness from which a declaration of invalidity or more may follow.<sup>67</sup> An example in the pharmaceutical arena of inadequate summaries being given to the ultimate decision maker is *SmithKline Beecham (NZ) Ltd v Minister of Health*.<sup>68</sup>

### Should a regulatory body consult when changing a pricing or subsidisation policy?

Authority exists for the proposition that a regulatory body should consult the pharmaceutical industry when changing a pricing, profit control or subsidisation policy. In *SmithKline Beecham (NZ) Ltd v Minister of Health*<sup>69</sup> SmithKline Beecham (SKB) sought to review the decision of the Minister of Health to reduce the subsidy payable for the antibiotic Augmentin to an amount based on the payment made for the

cheaper generic antibiotic Amoxycillin. Prior to that decision SKB, in reliance on a policy no longer in force, had been attempting to persuade the Department of Health that Augmentin was superior to Amoxycillin and therefore entitled to a higher subsidy. However, unknown to SKB, those particular pharmaceuticals were being grouped in accordance with a different policy then being introduced, the uniform pricing policy. The High Court set aside the Minister's decision. The cumulative effect of SKB's absence of knowledge of the policy on which the Minister was to act and the failure of the Minister to be adequately apprised of SKB's case meant that his decision was flawed and should be reviewed. As regards the change of policy, Greig J agreed with the applicant's submission that the Minister was obliged to inform the applicant 'about the details of the policy, in the form to which it had been changed, so as to give it an opportunity to make submissions on the application or the reasons for the non-application of the policy to the circumstances of the case'.<sup>70</sup> He added that this was 'all the more important where... the party, SmithKline Beecham, has been, with its predecessors, a frequent applicant in respect of various drugs, and in particular this drug, under a policy which undergoes a substantial change'.<sup>71</sup> Later in his judgment Greig J addressed and agreed with the applicant's related 'submission that the formulation, and presumably future development, of a policy such as the Uniform Pricing Policy should take place after consultation with interested parties'.<sup>72</sup>

### Conclusion

The advent and functions of NICE give rise to significant financial implications and pose many challenges for the pharmaceutical industry. Although NICE is in its infancy, its decisions are already having an effect. It is likely that NICE will be asked to appraise an increasing number of pharmaceuticals and that at least some of those will be the subject of recommendations contrary to the interests of the industry or at least individual suppliers as well as certain

patient groups. Appeals to NICE's Appeal Panel are already being made and applications for review in the High Court are a real possibility if not probability. Although NICE may, if it acts rationally, feel fairly comfortable about at least some of the substantive elements of its decision making, it is vulnerable to procedural challenge if it fails to comply with the legitimate expectations it creates and the other procedural obligations to which it is subject.

### Acknowledgement

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### Postscript

Immediately prior to publication, significant changes to NICE's procedures (forecast in the body of this article) were approved by the Board of NICE. First, the Board confirmed its decision of November 2000 to remove the confidentiality currently attaching to provisional and final appraisal determinations. Secondly, the Board approved the draft 'Revised Guidelines for Manufacturers and Sponsors of Technologies Making Submissions to the Institute' (now called 'Technical Guidance for Manufacturers and Sponsors'). Thirdly, the Board approved the draft 'Guide to the Technology Appraisal Process'.

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### References and notes

1. New Zealand, Australia and Canada are the main sources of this jurisprudence as for many years they have operated reference-pricing and other policies designed to control the escalation of government pharmaceutical expenditure (some additional jurisprudence is found in a handful of analogous cases from the Courts of England and the European Union). For example, New Zealand's Pharmaceutical Management Agency Limited (PHARMAC), the government agency responsible for operating and managing the Pharmaceutical Schedule which lists state-subsidised pharmaceutical products, has used a reference pricing policy as one of a number of means of controlling pharmaceutical expenditure. In Australia, subsidies for pharmaceuticals under the Pharmaceutical Benefits Scheme are in some instances regulated by a generic pricing policy and in others by a reference pricing policy introduced in 1998 known as the therapeutic group premiums policy. British Columbia, Canada, also operates a reference pricing policy.
2. National Institute for Clinical Excellence (Establishment and Constitution) Order 1999, article 3, as amended by the National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 1999.
3. [www.nice.org.uk/nice-web/](http://www.nice.org.uk/nice-web/)
4. 'Appraisal of New and Existing Technologies: Interim Guidance for Manufacturers and Sponsors' (December 1999): [http://www.nice.org.uk/nice-web/Embcat.asp?page=oldsite/appraisals/apr\\_guide.htm](http://www.nice.org.uk/nice-web/Embcat.asp?page=oldsite/appraisals/apr_guide.htm). See also 'Faster Access to Modern Treatment: How NICE Appraisal Will Work', (NHS Executive Discussion Paper, January 1999), Annex B: <http://www.doh.gov.uk/nice/appraise.htm>.
5. 'Faster Access to Modern Treatment', above note 4, para 44(i).
6. 'Faster Access to Modern Treatment', above note 4, Annex B, para 4(i).
7. 'Memorandum of Understanding on Appraisal of Health Interventions', (DOH, August 1999) para 10 (see <http://server1.nice.org.uk/nice-web/Article.asp?a=654&ss=memorandum%20of%20understanding>); 'Appraisal of New and Existing Technologies': above note 4, p. 1.
8. 'Memorandum of Understanding', above note 7, para 11; 'Appraisal of New and Existing Technologies', above note 4.
9. Above note 4. For new technologies, they are summarised at [http://www.nice.org.uk/nice-web/Embcat.asp?page=oldsite/nice/nic\\_summapp.htm](http://www.nice.org.uk/nice-web/Embcat.asp?page=oldsite/nice/nic_summapp.htm)
10. Guidance on the appeals procedure is found in NICE's 'Appeal Against Guidance to the NHS on a New or Existing Technology: Guidance for Appellants': see [http://www.nice.org.uk/nice-web/Embcat.asp?page=oldsite/appraisals/guide\\_appellants.htm](http://www.nice.org.uk/nice-web/Embcat.asp?page=oldsite/appraisals/guide_appellants.htm). The 'appeals' procedure is not an appeal on the merits. It is more akin to an appeal against the exercise of a discretion. The grounds are limited to (or are possibly more limited than) those available by way of judicial review. The 'Guidance' states expressly that, although the appellant may be legally represented, it is not intended that the hearing will be conducted in an adversarial manner. Rather, it will be conducted in an inquisitorial style. The Appeal Panel may also have a legal adviser present.
11. See *Pharmaceutical Management Agency Ltd v Roussel Uclaf Australia Pty Ltd* [1998] NZAR 58, 65 (CA) on the reviewability of PHARMAC. See also the High Court's discussion: *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd* (unreported, 13th August, 1997, High Court Wellington CP9/96, pp. 14–17).
12. *Hoechst Marion Roussel (NZ) Ltd v Pharmaceutical*

- Management Agency Ltd* (unreported, 25th June, 1998, High Court Wellington, CP13/98).
13. National Institute for Clinical Excellence Regulations 1999, reg. 13.
  14. See, eg, *R v Monopolies and Mergers Commission, ex parte Brown (Mathew)* [1987] 1 WLR 1235; *R v General Medical Council, ex parte Colman* [1989] COD 313 (HC); [1990] 1 All ER 489 (CA); *R v Worthing Borough Council and Secretary of State for the Environment, ex parte Burch* (1985) 50 P&CR 53.
  15. Above note 13, reg. 8(3).
  16. *Bryan v United Kingdom* (1995) 21 EHRR 342, 359. See further Richards, S. (1999), 'The Impact of Art. 6 of the ECHR on Judicial Review' JR 106, 108.
  17. See, eg, *R v Panel on Take-overs and Mergers, ex parte Guinness Plc* [1990] 1 QB 146, 177–178 (CA).
  18. *R v Leeds City Council, ex parte Hendry* (1994) Admin LR 439, 443.
  19. *Sakala v Secretary of State for the Home Department* [1994] Imm AR 227, 231.
  20. *R v Devon County Council, ex parte Baker & Johns* [1995] 1 All ER 73, 87.
  21. *O'Reilly v Mackman* [1983] 2 AC 237 (HL); *Minister for Immigration Local Government and Ethnic Affairs v Taveli* (1990) 94 ALR 177; *Minister of Energy v Petrocorp Exploration Ltd* [1989] 1 NZLR 348, 353 (CA); *NZ Fishing Industry Association v Minister of Agriculture and Fisheries* [1988] 1 NZLR 544, 554 (CA).
  22. Lewis, C. (2000), 'Judicial Remedies in Public Law', 2nd edn, Sweet & Maxwell, London, pp. 301–302.
  23. *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd* (unreported, 16<sup>th</sup> December 1996, High Court Wellington, CP 9/96) pp. 2–3.
  24. *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd* [1997] 1 NZLR 650, 658 (CA). See also Taylor, G. D. S. (1998), 'Administrative Law', New Zealand Law Rev. 403, 411; *R v Medicines Control Agency, ex parte Pharma Nord Ltd* [1999] EuLR 8 (HC and CA).
  25. See the last paragraph of part 5 of NICE's 'Guidance for Appellants', above note 10.
  26. Aldous, G. and Alder, J. (1985), 'Applications for Judicial Review', 2nd edn, Butterworths, London, p. 163.
  27. Above note 24.
  28. [1999] 1 WLR 927, 946.
  29. Unreported, 8th December, 1999, Federal Court of Australia (available via <http://www.austlii.edu.au/>). See also *Pharma Nord*, above note 24, p. 18.
  30. See *R v West Sussex Quarter Sessions, ex p Albert and Maud Johnson Trust Ltd* [1974] 1 QB 24, 39, 42 and, in particular, *R v Secretary of State for the Environment and anor, ex p Powis* [1981] 1 WLR 584 (CA). See also the thorough discussion in Fordham, M. (2000), 'Fresh Evidence in Judicial Review' JR 18.
  31. See, eg, *R v North and East Devon Health Authority, ex parte Coughlan* [2000] 2 WLR 622 (CA).
  32. Above note 11. See also *Reckitt & Colman (New Zealand) Ltd v Pharmaceutical Management Agency Ltd* [1997] NZAR 464 (HC).
  33. Above note 11, pp. 30–31.
  34. Above note 11, p. 32.
  35. Above note 11, pp. 34–36.
  36. Above note 11, pp. 62, 65, 66–70.
  37. (1991) 4 TCLR 170, 182 (HC).
  38. (1992) 88 DLR (4th) 763 (Ontario Divisional Court).
  39. Unreported, 23rd July, 1993, High Court, Lexis transcript. Other aspects of this case formed the subject of a reference to the ECJ: *R v Licensing Authority of the Department of Health and Norgine Ltd ex parte Scotia Pharmaceuticals Ltd* [1995] 3 CMLR 657.
  40. Above note 24. See also *R v Secretary of State for Health, ex parte RP Scherer Ltd* [1998] EuLR 1, 14 (HC).
  41. (1996) 135 DLR (4th) 587 (BCSC); (1997) 149 DLR (4th) 613 (BCCA).
  42. [1992] NZAR 357 (HC).
  43. Above note 11; unreported, 30th July, 1998, Privy Council Appeal No. 34 of 1998.
  44. (1989) 19 ALD 162 (FCA).
  45. Above note 43.
  46. (1996) 42 ALD 540 (FCA).
  47. Above note 32.
  48. Unreported, 20th March, 2000, Federal Court of Australia, 1120/1999.
  49. (1999) 7 Lloyd's Rep Med 289; (2000) 51 BMLR 189.
  50. Pricing and profit controls for prescription branded pharmaceuticals are governed primarily by the non-statutory Pharmaceutical Price Regulation Scheme (PPRS) which 'sets out rules to determine the maximum prices that may be charged by any scheme member in respect of health service medicines, and the maximum profits to be made from the sale of medicines covered by the scheme': 'The Pharmaceutical Price Regulation Scheme' (July 1999, p. 5). The text of the scheme is available at: <http://www.doh.gov.uk/pprs/index.htm>. Should scheme members fail to comply with the PPRS then under the Health Act 1999 they face the possibility of statutory controls on their prices and profits. Suppliers of branded pharmaceuticals who are not scheme members or who lose or withdraw their membership are now subject to the price controls in the Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000. Similarly, maximum prices for certain generic medicines supplied for use in the NHS have now been set by the Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000.
  51. That is, decisions to include them in Schedules 10 or 11 to the National Health Service (General Medical Services) Regulations 1992. Medicines listed in Schedule 10 cannot be prescribed at NHS expense whilst those listed in Schedule 11 may only be prescribed for certain conditions. The criteria for adding a product to these Schedules, as notified to the European Commission under Article 7 of the Transparency Directive (89/105/EEC), are listed in the Drug Tariff: see, eg, p. 533 of the April 2000 edition.
  52. See, eg, *SmithKline Beecham*, above note 42; deSmith, S., Woolf, H. and Jowell, J. (1995) 'Judicial Review of Administrative Action', 5th edn, Sweet & Maxwell, London, pp. 377–379, 403–407; Taylor, G.

- D. S. and Radich, P. J. (1997), 'Judicial Review Supplement' Butterworths, Wellington, para 13.57; *Nicholls v Health and Disability Commissioner* [1997] NZAR 351, 369-370 (HC).
53. See summary above of the Appraisal Process. See further 'Memorandum of Understanding', above note 7, paras 3-4, 7 and 12; 'Appraisal of New and Existing Technologies', above note 4, p. 2.
54. See *Wellington International Airport Ltd v Air New Zealand* [1993] 1 NZLR 671, 674-675; *R v Secretary of State for Social Services, ex parte Association of Metropolitan Authorities* [1986] 1 WLR 1, 4, 6-7 (QB); *Re Pergamon Press Ltd* [1971] Ch 388, 399-400 (CA); *R v Secretary of State for Transport, ex parte Richmond-Upon-Thames London Borough Council (No. 4)* [1996] 1 WLR 1460, 1474 (CA); *R v Barnet London Borough Council, ex parte B* [1994] 1 FLR 592; *Ozmanian v Minister for Immigration, Local Government and Ethnic Affairs* (1996) 137 ALR 103, 122-123 (FCA); *Pfizer Pty Ltd v Birkett*, above note 48, paras 114-131.
55. Above note 11.
56. Above note 11, 32.
57. Above note 11, 70.
58. *R v Secretary of State for Health, ex parte United States Tobacco International Inc* [1992] 1 QB 353, 370-371 (HC).
59. See *R v Secretary of State for Health, ex parte RP Scherer Ltd*, above note 40, in which a failure to communicate the results of a Government laboratory report to the applicant before the final decision was reached was held not to be procedurally unfair. See also *Pfizer Pty Ltd v Birkett* on the permissible relevance of drawing on a decision-making Committee's own expertise without communicating that (obvious) fact to consultees: above note 48, paras 134-139.
60. *Greenpeace New Zealand Inc v Minister of Fisheries* (Unreported, 27th November, 1995, High Court Wellington, CP 492/93); *United States Tobacco*, above note 58.
61. *Wellington International Airport*, above note 54; *Association of Metropolitan Authorities*, above note 54, p. 6; *Port Louis Corporation v Attorney-General of Mauritius* [1985] AC 1111, 1133 (PC).
62. *Wellington International Airport*, above note 54, pp. 680, 682-684; *Hamilton City v Electricity Distribution Commission* [1972] NZLR 605, 643 (SC).
63. *Wellington International Airport*, above note 54, pp. 674, 675, 676; *Auckland City Council v Auckland Electric Power Board* (unreported, 16th August, 1993, High Court Auckland, CP 26/93, p. 25); *Devonport Borough Council v Local Government Commission* [1989] 2 NZLR 203, 207-208 (CA); *R v Secretary of State for Health, ex parte London Borough of Hackney* (unreported, 25th April, 1994, QB, Lexis transcript).
64. *Auckland Electric Power Board*, above note 63; *Devonport Borough Council*, above note 63, pp. 207-208.
65. Above note 37.
66. Above note 37, p. 180.
67. See, eg, *Tobacco Institute of Australia Ltd v National Health and Medical Research Council* (1996) 142 ALR 1 (FCA). See further Taylor, G. D. S. and Radich, P. J. (1991), 'Judicial Review: A New Zealand Perspective', Butterworths, Wellington, pp. 281-286.
68. Above note 42.
69. Above note 42.
70. Above note 42, p. 367. In support His Honour referred to *R v Port of London Authority, ex parte Kynoch Ltd* [1919] 1 KB 176, 184; *R v Criminal Injuries Compensation Board, ex parte Ince* [1973] 1 WLR 1334, 1345; *British Oxygen Co Ltd v Minister of Technology* [1971] AC 610, 625 (HL).
71. Above note 42, p. 368. On this point see further *Glaxo New Zealand*, above note 37, p. 178 (HC).
72. Above note 42, p. 375. The approach in the *SmithKline Beecham* case may be compared with *Pharmaceutical Manufacturers Association of Canada v Attorney-General for the Province of British Columbia*, above note 41, in which the British Columbia Supreme Court and the Court of Appeal for British Columbia held that the applicants had no right to be consulted on the application of a new reference pricing policy to the applicants' products. In the author's view, the *SmithKline Beecham* case is preferable and is more likely to be followed in England than the *Pharmaceutical Manufacturers Association* case.