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*(subject to editorial corrections)**

IN THE HIGH COURT OF JUSTICE IN NORTHERN IRELAND

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QUEEN'S BENCH DIVISION (JUDICIAL REVIEW)

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Pharmaceutical Contractors Committee (NI) Ltd, Gordons Chemists and Medicare Pharmacy Groups' Application [2010] NIQB 3

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW BY

1. THE PHARMACEUTICAL CONTRACTORS COMMITTEE (NI) LTD

2. N & R GORDON LTD TRADING AS GORDONS CHEMISTS

3. MAGIR LTD TRADING AS MEDICARE PHARMACY GROUP

AND IN THE MATTER OF DECISIONS OF THE DEPARTMENT OF HEALTH, SOCIAL SERVICES AND SAFETY

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MORGAN LCJ

[1] The applicants are the Pharmaceutical Contractors Committee (NI) Ltd (PCC), the representative body for community pharmacies providing services under the National Health Service in Northern Ireland, and 2 companies which own and operate community pharmacies throughout Northern Ireland. The challenge concerns the lawfulness of the arrangements currently maintained by the Department of Health, Social Services and Public Safety (the Department) for the remuneration of community pharmacies in respect of dispensing drugs. The applicants are represented by Mr Larkin QC and Mr Scoffield and the respondent by Mr McClean QC and Mr McMillen. I am grateful to all counsel for their helpful oral and written submissions.

The statutory background

[2] At all material times the Department was under a target duty to provide or secure the provision of integrated health services in Northern Ireland through the prevention, diagnosis and treatment of illness by virtue of

article 4 of the Health and Personal Social Services (Northern Ireland) Order 1972 (the Order). Article 6 (1) of the Order required the Department to secure the provision of pharmaceutical services in accordance with part VI of the Order which deals with general health services. Article 55, within part VI, provides for the recognition by Health and Social Services Boards of a Local Pharmaceutical Committee being representative of the persons providing pharmaceutical services in the area. It is common case that the first named applicant is the Local Pharmaceutical Committee for the purpose of these proceedings. Article 55A of the Order provides that Regulations may require a Health and Social Services Board in the exercise of its functions under part VI to consult committees recognised by it on such occasions and to such extent as may be prescribed.

[3] The Department has various general powers in respect of the making of Regulations and in particular Article 63 of the Order deals with the arrangements for pharmaceutical services. By virtue of Article 63 (3) of the Order the Department is required to consult such organisations as appear to it to be representative of the pharmaceutical profession before making Regulations under that Article. The Regulations with which this application is concerned are the Pharmaceutical Services Regulations (Northern Ireland) 1997 (the 1997 Regulations) which were made after consultation with the Local Pharmaceutical Committee as required by the Order. Regulation 9 deals with the Department's obligation to compile and publish a Drug Tariff.

> "9(1) For the purpose of enabling arrangements to be made for the provision of pharmaceutical services, the Department shall compile and publish a statement (in these Regulations referred to as "the Drug Tariff") which it may amend from time to time and which, subject to paragraph (2), shall include-
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> (a) the list of appliances;
> (b) the list of chemical reagents;
> (c) the list of drugs for the time being approved by the Department for the purposes of Particle 63 of the Order;
> (d) the prices on the basis of which the payment for drugs and appliances ordinarily supplied is to be calculated;
> (e) the method of calculating the payment for drugs not mentioned in the Drug Tariff;
> (f) the method of calculating the payment for containers and medicine measures;
> (g) the dispensing or other fees payable in respect of the supply of drugs and appliances and of the

provision of supplemental services and of additional professional services;
(h) arrangements for claiming fees, allowances and other remuneration for the provision of pharmaceutical services; and
(i) the method by which a claim may be made for compensation for financial loss in respect of oxygen equipment.

(2) The Drug Tariff may state in respect of any specified fee falling within paragraph (1) (g), or any other specified fee, allowance or other remuneration in respect of the provision of pharmaceutical services by chemists, that the determining authority for that fee, allowance or other remuneration for those chemists is the Board, and in such a case paragraphs (4) and (5) shall apply.

(3) The prices referred to in paragraph (1) (d) may be fixed prices or may be subject to monthly or other periodical variations to be determined by reference to fluctuations in the cost of drugs and appliances.

(4) The Board shall consult the Local Pharmaceutical Committee before making any determination by virtue of paragraph (2).

(5) A determination made by the Board by virtue of paragraph (2) shall include the arrangements for claiming the specified fees, allowances or other remuneration, and shall be published by the Board in such manner as it seems suitable for bringing the determination to the attention of the chemists in its period."

There was some debate between the parties about the extent to which this Regulation imposed an obligation to consult the Local Pharmaceutical Committee in relation to the prices on the basis of which the payment for drugs and appliances ordinarily supplied is to be calculated. I am satisfied that whereas the Regulation expressly provides for consultation in respect of dispensing or other fees determined by the Board under Regulation 9(2) no such obligation is expressly or impliedly imposed on the Department in relation to its determination of the prices on the basis of which payment for drugs and appliances ordinarily supplied is to be calculated in accordance with Regulation 9(1) (d) and Regulation 9(3) of the 1997 Regulations.

[4] Schedule 2 of the 1997 Regulations set out a series of matters which are deemed to form part of the terms of service for chemists. By virtue of paragraph 2 of the Schedule a chemist must with reasonable promptness supply drugs or medicines ordered. A chemist may not give, promise or offer to any person any gift or reward as an inducement to or in consideration of his presenting an order for drugs on a prescription form. Paragraph 3 requires a pharmacist to provide pharmaceutical services and exercise any professional judgment in conformity with the standards generally accepted in the profession. Paragraph 4 deals with the hours during which premises must be open and paragraph 5 deals with the extent of supervision required for those who supply drugs. Paragraph 8 requires a chemist to make available records in relation to the supply of drugs and paragraph 9 deals with the remuneration of chemists.

> "9(1) The Board shall make payments, calculated in the manner provided by the Drug Tariff or in accordance with any determination made by virtue of regulation 9(2) (subject to any deduction required to be made by regulations made under Article 98 of, and Schedule 15 to, the Order) to chemists in respect of drugs and appliances, containers, medicine measures and dispensing or other fees.
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> (2) The Board shall make such payments, if any, at or provided for by the Drug Tariff or in accordance with any determination made by virtue of regulation 9(2) to chemists who provide additional professional services.
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> (3)Where a chemist so requests, the Board shall afford him reasonable facilities for examining all or any of the forms on which the drugs or appliances supplied by him were ordered, together with particulars of the amounts calculated to be payable in respect of such drugs and appliances and the Board shall take into consideration any objections made by the chemist in relation to those amounts.
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> (4) Where so requested by the Local Pharmaceutical Committee or any organisation which is, in the opinion of the Department, representative of the general body of chemists, the Board shall give the Local Pharmaceutical Committee or the organisation in question similar facilities for examining such forms and particulars mentioned in subparagraph (3)

relating to all or any of the chemists which it represents.

(5) If the Department, after consultation with any organisation mentioned in subparagraph (4) and with the Pharmaceutical Committee constituted in accordance with regulation 13 and Schedule 5, is satisfied at any time that the method of payment provided for in this paragraph is such that undue delay in payment may be caused thereby, it may direct that the amounts to be payable to a chemist shall be calculated by such other method, whether by averaging the amounts payable to a chemist or otherwise, as may appear to the Department to be designed to secure that-

(a) payment may be made within a reasonable time; and

(b) that payments to a chemist shall, as nearly as may be, remain the same as if the payments had been calculated in accordance with the first mentioned method of payment, and payments calculated by any such other method shall be deemed for all purposes to be payments made in accordance with these Regulations."

Paragraph 11 deals with the obligation to establish and operate a procedure to deal with complaints and provides for record keeping in relation to such complaints. Paragraph 12 imposes a duty on a chemist to co-operate with any investigation of a complaint by the Board.

[5] This statutory background makes plain that the provision of pharmaceutical services is highly regulated both in relation to the manner in which pharmacists are required to provide their services and the manner in which they are to be remunerated for those services. The 1997 Regulations impose the obligation to compile and publish the Drug Tariff upon the Department and Regulation 9(3) provides the basis upon which periodical variations of the prices may be determined. Those variations are to be determined by reference to fluctuations in the costs of drugs and appliances. The entirety of the statutory scheme makes it clear that the purpose of the publication of the Drug Tariff is to ensure that pharmacists receive fair and reasonable remuneration for the services and materials provided by them. The provisions in Paragraph 9 of Schedule 2 of the 1997 Regulations in relation to delay in payment also make it clear that it was the statutory

intention that the fair and reasonable remuneration should be paid in a timely fashion.

The history of the dispute

[6] The dispute is concerned with the price for generic drugs which are set out in Category M of the Drug Tariff. Although there is clearly a common interest throughout the United Kingdom in establishing a system of pricing the reimbursement of pharmacists was a devolved matter and was separately administered by the relevant Departments in Scotland and Northern Ireland. In 1994 the Department agreed with the PCC that the Northern Ireland Drug Tariff should follow the Scottish Drug Tariff which in turn followed that published by the Department of Health in England. There was considerable turbulence in the generics drug market in 1999 and in July 2001 the Department of Health published a discussion paper which considered options for reimbursement in respect of generic medicines. The discussion paper suggested that there were clear indications that many reimbursement prices were significantly above real market prices. Pharmacists did not share information in relation to the prices actually paid to the wholesalers with the Department and that remains the position in Northern Ireland.

[7] In 2003 the Department of Health in London and the Scottish Executive Health Department consulted on proposals to establish revised reimbursement arrangements for community pharmacy contractors on the basis that the prices for Category M generic drugs would be reduced so as to reflect a price closer to actual cost and additional monies were then provided for various contractual services to be provided by pharmacists. In order to establish the appropriate prices for inclusion in the Drug Tariff the Department of Health used its reserve powers to establish from wholesalers the prices at which generic drugs were generally being supplied to the pharmacy community in England, Wales and Scotland. This exercise also involved an estimation of the volumes of drugs supplied since this was relevant to the overall reimbursement of the pharmacists.

[8] The Department indicated its broad agreement with the objectives of the Scottish Executive Health Department and invited representations from the PCC in November 2003. No information gathering exercise had been carried out in relation to wholesale prices or volumes of generic drugs in Northern Ireland. The PCC noted that such an exercise was likely to place a significant administrative burden upon those involved. In 2004 the Department and the PCC began discussions on new contractual arrangements which the Department hoped to phase in from April 2005. Some progress was achieved in those discussions. Mr Robinson, who is the Assistant Director in the Department, deposed that in October 2005 the Department was trying to put something in place by April 2006. Against that timescale a

separate Northern Ireland Drug Tariff could not be developed because of the considerable time and resources required. A pharmaceutical cost enquiry was commenced in January 2006 and a report was prepared in July 2006. At a meeting in November 2006 the Department indicated it was still giving consideration to the introduction of a separate Drug Tariff for Northern Ireland.

[9] The new contract arrangements had come into force in England in April 2005 and were phased-in in Scotland after April 2006. The effect of the new arrangements was to reduce the prices for generic drugs in Category M. In Scotland the prices included in the Drug Tariff were based on information available in respect of wholesale prices and volumes within that jurisdiction. The new contract arrangements also provided additional remuneration opportunities for pharmacists. In light of the pre-existing arrangement in relation to the use of the Scottish Drug Tariff the Department continued to remunerate pharmacists on the basis of the revised Scottish Drug Tariff while recognising that this model was not suitable for Northern Ireland and resulted in considerable losses to pharmacists in this jurisdiction. In July 2007 the Department eventually agreed a figure in excess of £6 million with the PCC for the year 2006/2007. This was based on a methodology devised by Kathryn Turner of the CSA at the request of the Department.

[10] Although the Department and the PCC continued to meet after July 2007 it is clear that there was little or no progress made in agreeing a new contractual approach. In its submissions to this court the Department contends that the PCC has set its face against entering into a new and comprehensive settlement with the Department in order to retain the commercial advantages it enjoyed prior to the impact of Category M. For its part the PCC complains that the Department has introduced a Drug Tariff which fails to fairly and reasonably remunerate pharmacists and continues to withhold the compensation which the PCC says is properly due to them.

[11] On 7 May 2008 Mrs Jendoubi of the Department wrote to Mr Hannawin of the PCC setting out her position on Category M.

> "You and your colleagues voiced concerns over how Category M is handled in Northern Ireland. It was acknowledged by all of us that the problems emerge mainly because of the difficulties in establishing a suitable methodology for determining the effect of Category M here. This has proven to be a real difficulty for us in the Department.
>
> We discussed at length the difficulties caused last year by Category M and how these might be resolved taking into account our respective positions. The

methodology developed by the CSA has indicated that the effect of Category M in Northern Ireland was at least £3 million in 2007/08.

Category M is of course driven by London and it is not serving Northern Ireland well. As we pointed out at the meeting, the uncertainties surrounding Category M demonstrate clearly the need for a new, robust, transparent system for drug pricing in Northern Ireland. This new system needs to be linked to remuneration for services. In other words, on the one hand community pharmacy needs to see clearly how profits from the purchase of drugs are being identified and treated; and on the other, the Department needs to see clearly the services which are obtained as a result of moving drug purchase money from reimbursement to remuneration.

On one point I think we are agreed: Category M is not fit for purpose for Northern Ireland and we need to replace it. It is my intention therefore that the past arrangements in relation to Category M will no longer apply in 2008/09 and that an alternative arrangement will be developed.

I am convinced that the new Generic Procurement process will deliver such a system and I am most keen that PCC work with us in developing this new system. Once again the interests of patients will be to the fore since the proposed initiative will provide a quality-driven process for drug procurement. But it will also offer considerable benefits to community pharmacists.

I propose that we move ahead on two fronts.

Firstly, on the basis that it has not been — and, we accept, in all likelihood will not be — possible to develop a sufficiently robust methodology for assessing accurately the Category M figure for Northern Ireland, PCC and the Department should agree in negotiation an appropriate figure for last year. In anticipation of this I have asked Kathryn Turner not to carry out any further work regarding the detailed information I understand you requested from her on market data and methodology related to

> Category M in Northern Ireland as at this point I do not think it offers us any hopes of a verifiable solution.
> However, at the same time I do appreciate the cash flow problems you so forcefully expressed on behalf of your members and on that basis I am prepared, as we discussed, to authorise the immediate release of £3 million to community pharmacy in respect of Category M. This is offered as an up-front, goodwill, practical gesture to meet immediate needs, and notwithstanding that PCC contend that the effect is greater than this; and concomitantly I would ask PCC to engage with us to negotiate a Category M settlement for 2007/08 over and above the £3m.
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> Secondly, PCC and the Department should actively engage to develop the replacement for Category M in Northern Ireland. This means developing the Generic Procurement initiative. As I said earlier this offers the best opportunity for a transparent, quality-driven drug procurement system aimed at delivering considerable benefits for both patients and community pharmacists. You agreed to come and hear more about the proposed system and I hope that it will be possible to arrange a suitable date for this meeting in the near future."

The applicants have placed considerable reliance on that portion of the letter which says that Category M was not fit for purpose and needed to be replaced. The respondent contended that this simply reflected the fact that the current arrangements had produced the unsatisfactory position of there being no new contract, no improved terms as to fees and other allowances and no accurate methodology to calibrate ex gratia payments.

[12] At the request of the parties I had allowed some time for discussion to see whether an agreement could be reached. That was not possible but at the end of the first day's hearing Mr McClean QC addressed the issue of compensation. He explained that the compensatory amount for 2006/2007 was a one-off payment. It had been achieved by looking at actual prices before Category M was introduced and making assumptions. He stated that the following year Ms Turner attempted to carry out the same exercise for 2007/2008. He submitted that it was not possible to use the same methodology for two independent reasons. Firstly he said that a further 83 new products had to be taken into account and some of these were high-volume and high-cost drugs. As the number of drugs within Category M becomes higher the reliability of the estimate reduces. Ms Turner was not

satisfied that it was proper to proceed. Secondly market forces mean that there are always fluctuations. Reliance on materials available for April 2005 would ignore those market forces and the CSA considered that it could not use the previous year's methodology.

[13] The following morning Mr McClean clarified the Department's position. He stated that the first stage was to arrive at a number representing the impact of Category M. For 2007/8 and 2008/9 it was not the Department's position that it would simply pay the Turner figure. He indicated that what it would do is make a payment which fairness requires it to make to address the position of Northern Ireland pharmacists. He could not say that this would be 100% of the Turner figure. The Department did not accept that fairness demands necessarily that all of the Turner figure should be paid. He said that the Department would, however, seek to identify a Turner figure with all its imperfections and that it would be as scientific as possible.

[14] The Department's position is also set out at paragraph 50 of his first affidavit by Mr Robinson. He acknowledged that there had been enormous problems in trying to calculate the effect of Category M price changes for Northern Ireland community pharmacists. He said that it was a Department of Health driven system which is geared to providing funding for the new community pharmacy contractual arrangements in England and Wales. The Department had no control over the operation of the system or access to the information on which decisions on drug pricing were taken. He contended that despite the problems that this had caused in the community pharmacy economy there was no obligation on the Department to make compensatory payments in respect of the resultant loss of profit margin for pharmacists. He did, however, record that the Department had consistently expressed its aim to ensure that community pharmacy was as far as possible not disadvantaged.

Consideration

[15] Regulation 9 of the 1997 Regulations imposes a legal obligation on the Department to compile and publish the Drug Tariff. The Regulation expressly provides that this obligation is to be carried out for the purpose of enabling arrangements to be made for the provision of pharmaceutical services. In order to determine the limits of the discretion available to the Department in carrying out this task it is necessary to examine the object and purpose of this statutory obligation (see Padfield v Minister of Agriculture Fisheries and Food [1968] AC 997). As is clear from the consideration of the statutory background above the terms of service on which pharmacists provide material and services are highly regulated in the public interest. The provisions in relation to remuneration in Regulation 9 and Paragraph 9 of Schedule 2 of the 1997 Regulations inevitably reflect the need to ensure that pharmacists are fairly and reasonably compensated in a timely fashion.

[16] In support of its case the Department has placed considerable reliance upon the commitment in 1994 by the first named applicant to follow the Scottish Drug Tariff in relation to Northern Ireland. The materials before me indicate that this was an arrangement which both the Department and the PCC considered fairly remunerated pharmacists until in or about 2001. Thereafter it appears that the Department became concerned that the remuneration was excessive as a result of the proposals published by the Department of Health. The Department sought to correct this by discussion but made no progress prior to April 2006. At that time Category M which had been just introduced in Scotland was introduced in Northern Ireland. It is common case that within a short time it became apparent that the Drug Tariff compiled and published from April 2006 on did not fairly and reasonably remunerate pharmacists. That is evidenced by the fact that the Department considered it necessary to make compensatory payment in excess of £6 million in respect of the year 2006/2007, that Mr Robinson accepted that there were enormous problems in trying to calculate the effect of Category M price changes for Northern Ireland community pharmacists and the acceptance by Mrs Jendoubi in her letter of 7 May 2008 that Category M was not fit for purpose for Northern Ireland and needed to be replaced. I do not accept the submission of the respondent that the comments in this letter are simply to be interpreted as a complaint about the fact that no new contractual agreement has been achieved.

[17] Once it became apparent to the Department that the Drug Tariff was not fulfilling its statutory purpose there was a legal obligation on the Department to take steps to achieve that purpose. I accept the submission of the Department that a commitment to a compensatory amount coupled with an attempt to negotiate a new contractual agreement represented an adequate basis upon which to seek to achieve the statutory objective. It is apparent, however, that the negotiations effectively broke down in or about February 2007 and that by May 2008 the Department had ceased work on trying to find a compensatory amount for the years 2007/2008 and 2008/2009. The reasons advanced in the submissions for this approach were contradictory as set out in paragraphs 12 and 13 above. It also appears from paragraph 50 of Mr Robinson's affidavit that the Department now considers that it has no legal obligation to pay the compensatory amount which is designed to secure fair and reasonable remuneration for pharmacists.

[18] In his submissions to me at the end of the first day Mr McClean QC suggested that the Department would either have to reach an agreement with the PCC on a compensatory figure or alternatively reach a conclusion itself as to the appropriate level of compensation. I consider that he is probably right in relation to the past periods but the Department also has a continuing obligation under Regulation 9 to compile and publish a Drug Tariff which satisfies the statutory object and purpose. The Department is not excused from its obligation by virtue of the fact that it cannot reach agreement with

the applicants. If the statutory obligation requires the Department to expend resources and time on carrying out investigations it must proceed to do so. I consider that the applicants have demonstrated that the Department is now failing to comply with the statutory obligation found in Regulation 9 of the 1997 Regulations and in those circumstances I make a declaration that the arrangements currently maintained by the Department of Health, Social Services and Public Safety for the remuneration of community pharmacies in respect of dispensing drugs are unlawful. That was the remedy for which Mr Larkin QC contended.

[19] The applicant also relied upon the failure of the respondent to consult. Although there was no statutory obligation to consult I consider that the applicants were persons liable to be directly affected by the effect of Category M and that the effect was of such significance for them that procedural fairness required that they should be in a position to make representations on their own behalf. I consider, however, that the real difficulty here was that the Department was wedded to the introduction of Category M whereas the applicants contended that the introduction of this arrangement was likely to prevent fair and reasonable remuneration. I do not consider that the applicants were in any sense unfairly taken by surprise by the Department's position. They were, however, in my view perfectly correct to point out that the Departmental position did not correspond with the statutory obligation. I do not consider that the submission on legitimate expectation adds anything to the Padfield point and the same is true for the convention argument. The argument in relation to executive approval was not pursued at the hearing.