Neutral Citation No. [2011] NIQB 132 | *Ref:* **TRE8399**

Judgment: approved by the Court for handing down | *Delivered:* **23/12/2011**

*(subject to editorial corrections)**

IN THE HIGH COURT OF JUSTICE IN NORTHERN IRELAND

QUEEN'S BENCH DIVISION (JUDICIAL REVIEW)

CPNI's Application [2011] NIQB 132

IN THE MATTER OF AN APPLICATION BY CPNI FOR JUDICIAL REVIEW

TREACY J

Introduction

[1] The applicant, CPNI, is a company limited by guarantee, which represents the owners of community pharmacies in Northern Ireland who provide pharmaceutical services under the National Health Service. It is the successor to the Pharmaceutical Contractors Committee (Northern Ireland) Ltd ("the PCC") which was the applicant in the related judicial review of ***Pharmaceutical Contractors Committee (Northern Ireland)*** **[2010] NIJB 3.** The present case is, in large measure, the sequel to that earlier application.

[2] The respondents are the Department of Health Social Services and Public Safety ("the Department") and the Health and Social Care Board ("the Board"). The Department has a statutory obligation to maintain and publish a Drug Tariff for Northern Ireland making provision, *inter alia,* for the prices to be paid to pharmacists for the supply of approved drugs; for the payment of dispensing fees to pharmacists for the supply of those drugs; and for the payment of other fees and allowances for providing certain other pharmaceutical services. The Department has power to amend the Drug Tariff from time to time. The function of the Board is to make arrangements for the delivery of pharmaceutical services in Northern Ireland.

[3] The applicant challenges the determinations made pursuant to Reg9 of the **Pharmaceutical Services Regulations (Northern Ireland) 1997** ("the 1997 Regulations") on prices and fees to be included in the Drug Tariff and a decision of the Department made on 24 March 2011 amending the said Drug Tariff with effect from April 1 2011.

Statutory Background

[4] The statutory background remains as it was at the time of the 2010 application. For ease of reference I have adopted and here reproduce the sections of the judgment of Morgan LCJ in that case which set out the relevant statutory background in the following terms:

> **"[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.** [In the present case that committee is the applicant, CPNI.] **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-
(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."**

[5] I also adopt the conclusion of the Lord Chief Justice in relation to the purposes of the publication of the Drug Tariff which he expressed as follows in para5 of his judgement:

> **"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. ..."**

Factual Background to the Current Dispute

[6] The factual background to the current case overlaps with that in the 2010 judicial review. That background is that certain market driven changes had taken place in the generic drugs market in 1999 as a result of which government departments responsible for the remuneration of pharmacists had formed the view that many of the reimbursement prices they were paying for generic drugs, also known as "Category M drugs," were significantly above real market prices. The relevant departments wished to revise the payments made in relation to Category M drugs to bring them more into line with actual costs paid by pharmacists to wholesalers for these drugs.

[7] The reimbursement of pharmacists is a devolved matter dealt with separately by the relevant departments in England and Wales, Scotland and Northern Ireland. In 2001 the Department of Health in England issued a discussion paper designed to realign reimbursement with costs paid. Pharmacists did not engage with this process and did not supply information in relation to the prices they paid to wholesalers for their Category M drugs. In 2003 the English Department of Health and its Scottish equivalent carried out a further consultation. On this occasion they used reserve powers to establish from wholesalers the prices at which generic drugs were generally supplied to pharmacists in England and Wales and in Scotland. No such information gathering exercise was carried out in Northern Ireland either in 2003 or at any time since.

[8] In 2005 a new pharmaceutical services contract was issued for England which did two important things. First, it provided additional remuneration opportunities for pharmacists and secondly, it revised downwards the prices to be paid for generic (Category M) drugs in England and Wales. These new contract arrangements were also phased into Scotland from 2006. In Northern Ireland an agreement had existed since 1994 between the Department of Health here and the then PCC whereby reimbursement for Northern Irish pharmacists would follow the Scottish model.

Following that agreement the Department applied the revised Scottish tariff to Northern Ireland from 2006 onwards, although it recognised that this model was not suited to Northern Irish conditions. The general consensus that the Scottish model did not provide appropriate remuneration for pharmacists in Northern Ireland led the Department here to introduce a compensatory scheme which applied only in this jurisdiction. This scheme was designed to top-up the payments made to local pharmacists under the terms of the Scottish tariff model when it was applied in Northern Ireland.

[9] The 2010 judicial review arose when the department sought unilaterally to withdraw the compensatory payment scheme without having first negotiated a new pharmaceutical contract or a revised Drug Tariff tailored to conditions in Northern Ireland.

[10] In finding for the applicants in the 2010 case the Lord Chief Justice stated:

> **"[18] ... 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. ..."**

[11] In the context of the department's withdrawal of the compensatory payment scheme and attempt to apply the Scottish model without adjustment to Northern Irish conditions the Lord Chief Justice stated:

> **"[18] ... 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. ..."**

The Interim Agreement

[12] The 2010 judgment gave rise to extensive negotiations between the applicant and the respondents resulting in the signing of an Interim Agreement in July 2010 the terms of which, so far as relevant, are set out below. In the Introduction it states:

> **"A management team comprising members of the Health and Social Care (HSC) Board, Business Services Organisation (BSO) and the Department for Health, Social Services and Public Safety (DHSSPS), (collectively the Management Team) has reached the following agreement with the Pharmaceutical Contractors Committee Limited (PCC) with respect to the qualification and discharge of a compensatory payment in respect of Category M drugs for the period 1st April 2007-31st March 2010 as following the judgement of Lord Chief Justice Morgan in the Judicial Review case. Agreement has also been reached in the treatment of the interim period until such times as a lawful Northern Ireland Drug Tariff is implemented. The interim period is from 01 April 2010 up to, but no later than 31 March 2011."**

[13] At para 4 it states:

> **"The treatment of the 2010/11 year will be regarded as a stand alone payment regime, and will apply for the whole or part of the 2010/11 financial year and would be paid for no longer than 12 months."**

[14] Paras 9-10 state:

> **"9. Interim payments are defined as non-recurrent monthly payments to individual contractors until such times as a Northern Ireland Drug Tariff is in place but no later than 31 March 2011.**
>
> **10. Some £6m has been made available for interim payments across the period 01 April 2010 to 31 March 2011. ... The payment regime for the interim period will be stand-alone, and made on a without prejudice basis until such times as a new Drug Tariff is in place."**

[15] Paras 13-14 provide:

> **"13. The interim period will be 1 April 2010 – 31 March 2011. It is incumbent on the relevant parties to work to ensure that a fair and reasonable remuneration model is in place by 31 March 2011. The Management Team will consult with PCC in the development of proposals for a Northern**

Ireland Drug Tariff and associated remuneration model.

14. If agreement cannot be reached the interim agreement falls and the Department will be legally obliged to implement a fair and reasonable solution as per the Judicial Review ruling. "

The Current Dispute

[16] During the currency of the Interim Agreement the Department sought to agree a new Drugs Tariff. This involved extensive consultation with the applicant, consideration of their representations and the commissioning of advice from independent external consultants. The applicant's agreement was not forthcoming and following the expiration of the Interim Agreement the new NI Drugs Tariff was introduced in purported discharge of the Departments statutory duty under Reg9. The applicant submits that it does not provide for fair and reasonable remuneration and accordingly fails to satisfy the statutory objectives as elucidated in the judgement of Morgan LCJ in the 2010 case. The applicant also challenges the impugned measure on an elaborate range of grounds which may be summarised into the following three main heads of challenge:

(i) That the respondents failed to take reasonable steps to acquaint themselves with relevant material and information before making the impugned determinations and failed to acquaint themselves with relevant material and information for the purpose of determining whether the proposed new Drug Tariff would represent fair and reasonable remuneration for pharmacists in Northern Ireland;

(ii) That the respondents' failure to conduct a Regulatory Impact Assessment ("RIA") in accordance with the Northern Ireland Guide for Better Policy Making and Regulatory Impact Assessment ("the RIA Guide") published by the Department of Enterprise, Trade and Investment amounted to procedural unfairness, and/or irrationality and/or unreasonableness, and that it failed to satisfy the applicant's legitimate expectation that an RIA would be undertaken;

(iii) That the respondents made the impugned determination before the expiry of the consultation period and without having regard to all representations submitted as part of the consultation and that this was therefore procedurally unfair.

Affidavit Evidence

[17] I now wish to consider the affidavit evidence in relation to the main areas of dispute between the parties, as summarised above.

Evidence re the alleged failure of the respondents to inform themselves adequately

[18] Mr Joseph Brogan, Assistant Director of Integrated Care with the Board swore a helpful affidavit in which he sets out a number of features of the operation of the Drug Tariff. At paras9-12 he stated:

> *"(a) Global Sum*
> **9. Payments made to pharmacists in Northern Ireland for providing dispensing services to National Health Service patients consist broadly of two separate elements:**
>
> **(i) <u>Annual Professional Practice Allowance</u>. Every contracted pharmacy in Northern Ireland receives an annual payment by way of contribution to the annual running costs of the pharmacy. This payment is a recognition of the fact that the pharmacy is an independent private sector business which also contributes to the provision of public health services. The current allowance is £13,000 per annum.**
>
> **(ii) <u>Dispensing Fee</u>. This is a fixed fee payable to each pharmacist for dispensing an approved drug or appliance to a National Health Service Patient. There are separate fees depending upon whether the prescription required a single or multiple dispensing transaction. Where a patient is vulnerable or the patient is receiving treatment with a drug and there is a known safety risk, a doctor may endorse a prescription with a recommendation that the course of medication should be dispensed in instalments. Depending upon how the prescription is written, the pharmacist will be entitled to claim a single fee or a multiple fee, which is a lower amount, payable on dispensing each instalment.**
>
> **The above represents a broad summary only of Board payments to pharmacists for dispensing. The detailed payment arrangements and rates are set out in Part 0 (i.e. the General Notes) of the Drug Tariff.**

(b) "Financial Envelope"

10. This is a phrase used to refer to the overall annual budget made available by the Department for the provision of community pharmacy services. It includes a number of components.

(i) Global Sum. This is the total investment made available to pharmacists for dispensing prescription drugs as described above. Budgetary provision of this sum is made by reference to the number of pharmacies which will receive an annual allowance and an estimate of the volume of prescriptions required for the population with prescribed medications. This figure can be estimated at the start of the financial year with a relatively high degree of accuracy, based upon population numbers, estimated need and historic pricing information.

(ii) Ancillary Services. In addition to payment for dispensing drugs, pharmacists are able to earn additional money from the Board by providing additional services to patients. A range of the type of services and remuneration rates are described in Part 0 of the Drug Tariff. They include matters such as out of hours services; grants for providing pre-registration training to non-qualified pharmacists; pharmacy advice service to nursing and residential homes; and provision of oxygen therapy equipment. Other services are not specified in the Tariff e.g. Managing Your Medicines Service; Needle and Syringe Exchange Service. These are managed through elective service contracts with the HSC Board.

(iii) Retained Purchase Profit. This is one of the most complex aspects of community pharmacy funding and is also one which had proved contentious during consultation with the Applicant. In summary, it has been proposed that this figure represents the allowed amount of profits which pharmacists can earn by procuring drugs at a price lower than the relevant reimbursement cost specified in the Drug Tariff. The

> **amount of retained purchase profit for the entire community pharmacy economy is estimated and a proportion included within the calculation of the overall annual investment. Since this is a cost which is ultimately borne by government through the price it pays pharmacists for drugs dispensed, it is accounted within the "financial envelope" for the community pharmacy annual budget.**
>
> **11. The publication of a Drug Tariff for Northern Ireland is therefore the mechanism by which government in Northern Ireland presents the prices for both reimbursing drugs dispensed in the community and also the rate of pay to pharmacists for dispensing those drugs. While this is the largest part of the budget, the community pharmacy economy as a whole also involves the provision of additional services by pharmacists for which additional remuneration is available.** ***It is recognised by government that if pharmaceutical services are to be delivered, in the main, through a network of independent private sector pharmacists, it is important that prices and budgets provide a level of financial incentive to continue providing the service while at the same time provide a mechanism to contain drug costs. For this reasons, government recognises that overall the prices and payment structures within the Drug Tariff should enable pharmacists to earn an element of profit on the wholesale prices at which they procure drugs. However, this must be balanced against the need for government both to obtain value for money and to operate within budgetary constraints. The manner in which these two objectives are met lies at the heart of the issues in this case."***

This section of Mr Brogan's affidavit is useful in clarifying the broad objectives of setting the Drug Tariff and I shall return to this again in my conclusions to this judgment.

[19] Mr Brogan is also helpful in explaining the respondents' conduct of the negotiations giving rise to the present challenge. At para12 of his affidavit he states:

> **"12. One of the most challenging aspects of setting a Drug Tariff is obtaining access to reliable and up to date market information on drug prices. There**

> **are many reasons for these difficulties, which include the following factors. First, there is a difference between the markets for generic and branded drugs. In general terms, branded drugs are ones which still benefit from patent protection. Prices are normally controlled by the manufacturer and there tends to be little or no competition. There tends to be one single price which is set by the manufacturer and is not contentious. Generic drugs are those for which patent protection has expired and which are manufactured by more than one company. Price competition therefore does exist for these products and tends to be controlled by market forces. Second, prices can change regularly and can be dependent upon national and global economic factors. Third, the price to individual pharmacists can depend upon the volume of drugs being purchased, hence larger pharmacies or groups can benefit from bulk purchasing. The market for generic drugs represents the greatest opportunity for individual pharmacists to earn additional profit from dispensing.** ***It also represents an area where price control for these drugs within the Drug Tariff affords government an opportunity to manage the levels of retained profit within the overall community pharmacy economy, thus balancing the need for pharmacists to earn a profit and government to achieve value for money in drug procurement."*** [Emphasis added]

[20] This paragraph makes it clear that during the present negotiations the respondents were aware of the importance of "obtaining access to reliable and up to date market information" which would enable them to achieve fairness in the balancing exercise they identify at the end of para12 of Mr Brogan's affidavit.

[21] Mr Brogan goes on to explain that, in order to inform work on the Drug Tariff, the respondents appointed an external consultant (Tribal plc) to provide advice. Tribal was asked to develop a methodology, model and working prototype:

(a) To support the development and ongoing maintenance of a new NI Drug Tariff. This was to be prepared in such a way that it could be adapted or reviewed in the future, to adapt to changing circumstances.

(b) To support the assessment of the return on investment which community pharmacists would require in order to achieve fair and reasonable funding for the delivery of their NHS Service Contract.

[22] The terms of reference given to Tribal were shared with the applicant in advance. A pre-report meeting also took place on 12 August 2010 at which representatives of the applicant were invited to meet with Tribal and to raise issues of concern to it about its report. Following the meeting the applicant submitted a detailed paper summarising its views on the issues discussed.

[23] Tribal submitted its report on 1 October 2010. Mr Brogan summarises the Tribal Report as follows at para 26(c) of his affidavit:

> **"26.(c) The clear and strong recommendation made by Tribal was to follow the Drug Tariff model which the Department ultimately introduced in April 2011, namely to adopt the reimbursement prices contained in the English Drug Tariff which are based upon known manufacturers prices. This model incorporates a "Category M" for generic drugs and also contains a fixed sliding scale discount based on the total value of drugs dispensed on a monthly basis.**
>
> **(d) A margins survey should be carried out in Northern Ireland with a view to ascertaining with greater accuracy the amount of retained purchase profit which the reimbursement costs in the English Drug Tariff delivers in Northern Ireland with subsequent adjustment of the discount scale to offer for increases or decreases in profit levels. ...**
>
> **(e) A summary of the recommendations contained in Chapter 9 is made in the following terms:**
>
> > **It is recommended that existing reimbursement arrangements are *modified to rely* to a large extent *upon* part viii of *the English Tariff as a reference source* for pricing information on generic medicines. *It is also recommended that* in order to ensure that the NI Drug Tariff continues to support fair and reasonable payment to contractors on an ongoing basis, *audits of pharmacy invoices (Margin Surveys) are undertaken to establish the levels of retained margin that pharmacy contractors are able to secure."*** [Emphasis added]

As Mr Brogan's evidence acknowledges, the Tribal report merely recommended that any amended N.I. Drug Tariff should adopt the English model as a **reference source** for drug prices. Tribal fully acknowledged that the English model needed to be

adjusted to take account of different conditions in N.I. and indeed identified quite specifically those areas in which detailed Northern Irish data needed to be gathered in order to facilitate the making of appropriate, informed adjustments.

[24] Mr Greene, Chief Executive of CPNI, provided evidence on how conditions differ for N.I. pharmacists as compared to their English counterparts. Para38 of his second affidavit, dated 12th September 2011 lists a range of ways in which the social, economic and general health conditions in N.I. are different from equivalent conditions in England. The general differences he identifies include the following factors:

- There are more pharmacies in NI than in England;
- The prescribing rate in N.I. is 23% higher than in England;
- There are higher levels of economic and social deprivation in N.I.;
- Health indicators such as mortality rate, death rate from coronary heart disease, prevalence of mental health problems and overall levels of health needs are all poorer in N.I.;
- NI has a 46% higher rural population than England;
- NI is still dealing with the legacy of the troubles which generates some duplication to ensure equity of access to pharmaceutical services for all communities.

[25] In addition to these differences in the background circumstances within which pharmacists must work, Mr Greene also identifies specific market differences which are likely to impact on the comparative levels of potential profitability of pharmacies in the two jurisdictions. For example para 38(f) of this affidavit states:

> **Although prices in the Northern Ireland Drug Tariff may be similar or the same as those in England, Mr Brogan does not mention that the Health and Social Care Board has encouraged prescribers to prescribe 'branded generics'. These are medicines that are out of patent, for which a competitor of the company owning the brand can make its own generic version available and give that version a brand name. If GPs prescribe the branded generic, pharmacies will only be able to supply the branded generic. ... Community pharmacy owners are generally unable to obtain discounts on branded medicines, so this impairs their ability to achieve purchase profits. The use of branded generics is not widespread in England. Ironically, it means that English prices are not, in fact, being paid in Northern Ireland because even lower prices for a range of branded generics are being paid instead.' [emphasis added].**

[26] It is important to note also that Tribal's report came with candid acknowledgements of the limitations it had to deal with in the information base available to it for conducting the work it had been commissioned to undertake. These limitations are set out as follows in **Chapter** 13 of the Tribal report:

> **"(e) One section of the English Drug Tariff is set using limited pricing information from four sources only,** ***which are not necessarily reflective of drug pricing throughout the market....'***
>
> **"(f) In England, pharmacists provide additional services under their National Health contracts and thus have available additional revenue sources. A new pharmacy contract is not yet in place in Northern Ireland. Additional constraints in preparing the report were future uncertainty over the level of government expenditure on medicines and limited data on the costs of running a pharmacy. ...**
>
> **(i)** ***An estimate of current profitability*** **levels within pharmacies in Northern Ireland** ***was carried out*** **in order to inform the potential impact of the proposed changes in the Drug Tariff [Chapter 11].** ***Limited information was available*** **to complete the exercise.** ***Data contained in the 2005/06 Northern Ireland costs ... survey was therefore used,*** **with appropriate adjustments to account for inflation etc. ...**
>
> **(j)** ***There was no evidence to suggest that the market in wholesale drug prices*** **or discounts** ***was any different in Northern Ireland*** **than elsewhere in the UK. [Paragraph 12.2]"**
> [Emphasis added]

It is notable that many of the core deficits identified by Tribal are deficits in the amount of basic relevant information available to inform the process of revising/adjusting the English Drug Tariff to make it fit for purpose in NI. While Tribal identify the areas in which core local data is missing their report does nothing to fill these information gaps as this exercise is not part of their remit.

[27] A copy of the Tribal report was sent to the applicant on 20 October 2010 and it was required to make its response by 20 January 2011. The applicant's evidence about its input into the information gathering exercise undertaken by the respondents is set out in Mr Greene's first affidavit dated 23 June, 2011. At para27 of this affidavit he states:

> **"In principle CPNI does not take issue with any of Tribal's key recommendations ... We also agree that, in order to reach a proper determination as to the contents of the Northern Ireland Drug Tariff, further work was necessary, namely, at the very least, (i) the proper identification of the factors which would require adjustment of the figures in the English Drug Tariff, (ii) the carrying out of a margins survey to properly understand the level of retained purchase profits, and (iii) a detailed cost survey to properly assess the cost to community pharmacies of providing their services."**

He continues:

> **"28. At a meeting on 23 November 2010, CPNI agreed with representatives of the department and its agencies to take forward proposals for a discount survey in Northern Ireland ...** ***At a meeting on the following day the department suggested that since the results of a survey showing the cost of providing NHS pharmaceutical services would not be available, when determining remuneration for 2011/12, reliance should be placed on data from a costs survey carried out six years earlier in 2005/06".***
> [Emphasis added]

[28] Mr Greene's evidence therefore accords with other evidence in this case indicating that no up to date cost survey was conducted prior to the introduction of the Drug Tariff of March 2011.

[29] In relation to the issue of the margins survey which had been recommended in the Tribal Report the applicant's evidence is as follows:

> **"No baseline survey and no margins survey has ever been carried out. This is because the department proposed to carry out a one off survey based on outdated methodology, and we repeatedly explained to the Department that relying upon a one-off snapshot to determine figures for an entire financial year risked giving a misleading picture, because circumstances are constantly changing. We were, and remain, willing to cooperate in a rolling margins survey". [para34 of 1st Affidavit of Mr Greene]**

[30] Reading this in conjunction with Mr Brogan's evidence it is clear that there is disagreement between the parties about the extent of CPNI's willingness to cooperate with a margins survey. However, there is agreement that (for whatever reason), no such survey was in fact conducted prior to the publication of the new Drug Tariff in March 2011.

Affidavit Evidence in relation to the Regulatory Impact Assessment (RIA)

[31] A further ground of conflict between the parties centres on the question whether or not an RIA should have been conducted prior to the introduction of the revised Drug Tariff. The department's position on this question is set out in an affidavit from Ms Emer Morelli, Principal Officer within the Medicines and Policy Group, Pharmacy Branch of the department. In her affidavit she sets out a history of RIA's in Northern Ireland pointing out that the requirement to conduct such assessments was initially limited to new regulatory measures introduced by means of legislation. She adds that since then various reviews were undertaken for the purpose of securing better practice in regulatory activity by government departments. One of these reviews was conducted in 2004 by the Department of Enterprise, Trade and Investment ("DETI"). On foot of this review this department published guidelines on the conduct of regulatory impact assessments entitled "Better Policy Making and Regulatory Impact Assessment: A Guide for Northern Ireland". Ms Morelli quotes para1.3 of these guidelines which states:

> **"1.3 In approving the better regulation strategy in December 2001, the Northern Ireland Executive underlined the existing requirement that no proposal for regulation, which has an impact on business, charities, social economy enterprises or voluntary bodies, should be considered by Ministers without a Regulatory Impact Assessment being carried out. A RIA is an integral part of the policy development process and advice that goes to Ministers."**

[32] Ms Morelli then considers whether an RIA was **necessary** in relation to the introduction of the amended Drug Tariff. In para15 of her affidavit she states that this new Drug Tariff "is not a piece of legislation and it has not involved the introduction of any new system of regulation. It has been implemented by means of ministerial announcement, coupled with the publication of the new tariff. Importantly, it has not involved any change in government policy". On this basis Ms Morelli considered that there was no obligation upon the department to conduct a RIA in relation to the introduction of the amended Drug Tariff.

[33] She does however state at para 17 of her affidavit:

> **"Notwithstanding the absence of any obligation to conduct a formal RIA, this does not mean that the**

> **department was not mindful of the potential impact upon pharmacies of the new Drug Tariff."**

At para 18 of her affidavit she states:

> **"The proposal for the introduction of the new Drug Tariff was also the subject of a high level economic appraisal and impact assessment. This is the first stage of the RIA process described in the DETI guidance document."**

At para 19 she continues:

> **"As described in earlier affidavits, a high level economic impact assessment was carried out, using the most up to date English drug prices which were available."**

She concludes in para 22:

> **"Even if the department is not correct in its view of the requirement for RIA, it is not accepted that a failure by it to conduct a full RIA was in any way unfair to the applicant, resulted in relevant information being left out of account or otherwise represented a legal basis of challenge to the introduction of the new Drug Tariff."**

[34] The applicant's evidence in relation to the RIA begins in para32 of Mr Greene's affidavit which states:

> **"At a meeting on 7 February 2011, CPNI negotiators asked whether an impact assessment had been carried out by the Board on the effects the proposed changes would have on a community pharmacy. The response from the Board's representatives, according to CPNI's notes of the meeting ... was that no assessment had been carried out in advance and as 'the Board don't have a clear understanding of what the effect the proposed changes would be at contractor level, that they instead 'wanted [CPNI] to provide feedback and a response to the consultation, which would in essence be the Impact Assessment."**

[35] Later in his evidence, in a section of his affidavit entitled "Exchanges subsequent to the decision", Mr Greene states that Dr Sloan Harper, Director of Integrated Care at the Health and Social Care Board said in a letter:

> **"... in relation to impact assessments, that the Board had been transparent and amenable to discussion with CPNI, and the impact of proposed changes was put forward to CPNI with the rationale and as much detail as possible. Dr Harper said the Board had 'continued to inform ongoing impact assessments' and that the Board had been 'transparent in how this information had been developed.'**

Commenting on these assertions Mr Greene states:

> **I have to say, I do not understand what Dr Harper means, and far from being transparent, his letter is opaque. Dr Harper referred to instances where an impact assessment would not be called for. However, the document Better Policy Making and Regulatory Impact Assessment: A Guide for Northern Ireland published by the Regulatory Impact Unit of the Department of Enterprise, Trade and Investment makes it clear not only that it is always good practice to produce a Regulatory Impact Assessment as a structured way to inform policy making, but '*all government departments and agencies where they exercise statutory powers and make rules with a general effect on others are required by Ministers to produce an RIA*. [Para1.6]**
>
> **And one *must* be prepared for 'all proposals (legislative and non-legislative), which are likely to have a direct or indirect impact, whether benefit or cost, on business." [para1.7]**
> **[para51 of Mr Greene's affidavit]** [Emphasis added]

[36] From the above evidence I conclude that the parties do not agree on whether or not an RIA was necessary prior to the publication of the new Drug Tariff, but do agree that no RIA was in fact conducted at that time.

Evidence in relation to the allegation that the impugned determination was made before the expiry of the relevant consultation period

[37] Mr Greene's evidence on this point begins at para30 of his first affidavit which states:

> **"On 18 January 2011 ... Dr Sloan Harper ... wrote to me with proposals for the community pharmacy pay offer for the 2011/12 financial year that would commence on 1 April 2011. This included proposals for fees that would be included in any new Drug Tariff.....Dr Harper invited CPNI's response before 15 March 2011, a bare 8 weeks later."**

[38] He continues:

> **"36. By 3 March 2011 I had not been able to respond to Dr Harper's letter of 18 January 2011, consulting CPNI on fees that would be included in the new Drug Tariff ... I did write to Dr Harper, however pointing out that a bare 8 weeks to respond was insufficient, and asking for 12 weeks in accordance with the Department's own guidance. Dr Harper replied on 7 March 2011 insisting that 8 weeks was a reasonable consultation period but agreeing to a 10 day extension to 25 March 2011.**
>
> **37. On 24 March 2011, I wrote to Dr Harper ... responding to his letter of 18 January 2011 ... I commented on the proposals for fee reductions which the Board had proposed and pointed out that if the Board had carried out an impact assessment, it had not been disclosed to CPNI and we would have wished to see it before responding to the consultation. ... I added that *CPNI was concerned that implementation of the proposed fees would be seriously damaging to the pharmacy network and the ability to provide pharmaceutical services.*** [Emphasis added]
>
> **38. On the same day as my letter to Dr Harper, the Minister announced that a new Northern Ireland Drug Tariff would be introduced with effect from 1 April 2011. ..."**

[39] The respondent's evidence in relation to the dispensing fees element of the Drug Tariff is presented in paras45-53 of the affidavit of Mr Joseph Brogan in the following terms:

> **"45. The dispensing fees and other allowances paid to pharmacists for dispensing drugs are specified within the Drug Tariff. In the new Drug Tariff**

these are set out in Part 0, Section 16... Pursuant to Regulation 9(2) of the 1997 Regulations, the relevant fees may be included within the Drugs Tariff and pursuant to Regulation 9(4) the Board must consult the Applicant before making any change to these fees and allowances. This statutory obligation to consult applies only in relation to dispensing fees/allowances. It does not extend to changes to reimbursement prices within the Drug Tariff itself.

46. A consultation process on the proposed new fee structure was conducted between January and May 2011. ...

47. The process commenced on 18 January 2011, when Dr Sloan Harper wrote to Mr Greene. The letter outlined the proposed changes and sought the views of the Applicant. ...

48. The Applicant was invited to respond to the consultation by 15 March 2011, ... The Applicant then requested additional time for its response and the consultation period was extended to 25 March 2011.

49. The Applicant submitted its response on 24 March 2011. ..."

[40] From these accounts I conclude that:

- The respondents recognised that they had a statutory duty to consult the applicant in relation to any proposed amendment to the dispensing fees element of the new Drug Tariff;

- The applicant was invited by the respondents to give its views on the new dispensing fee proposals and it was agreed between the parties that the consultation period for this aspect of the revised Drug Tariff would run until 25 March 2011;

- The applicant made its representations on this issue on 24 March 2011 and on the same day the Minister announced the publication of the new Drug Tariff.

- The respondents then proceeded as if the consultation period extended until May 2011.

For completeness I should add the following piece of evidence from para53 of Mr Brogan's affidavit:

> **'In light of the agreed extension of the fees consultation period until 25 March 2011 it was not possible to introduce any changes to dispensing fees on 1 April 2011 at the same time as the new Drug Tariff. For this reason, the original fees within the Interim Agreement were continued until such time as the Board had approved the new fee structure. The new fees did not come into operation until 1st June 2011 ..."**

and

> **"For all the reasons set out above, the consultation on dispensing fees was a different and distinct process to that on the proposal to reform the Drug Tariff. In any event, the introduction of the new dispensing fees was deferred until such time as approved by the Board. It is also clear that all representations made ... were given full consideration by the Board."**

Discussion

(i) The alleged failure of the respondents to inform themselves adequately

[41] It is uncontroversial that the department, as a public body, has a duty to make sufficient enquiry. A public body has a basic duty to take reasonable steps to acquaint itself with relevant material. In ***Secretary of State for Education and Science v Thameside MBC*** **[1977] AC 1014** Lord Diplock said:

> **"The question for the Court is, did the Secretary of State ask himself the right question and take reasonable steps to acquaint himself with the relevant information to enable him to answer it correctly?" [1065B]**

[42] To similar effect in ***R (DF) v Chief Constable of Norfolk Police*** **[2002] EWHC 1738 (Admin)** the Court stated at para45 that:

> **"A decision maker has an obligation to equip himself with the information necessary to make an informed decision".**

See also Judicial Review Handbook, 5th Ed, Michael Fordham at para51.1 *et seq*.

[43] On the basis of the evidence summarised above I consider that the respondents have not taken sufficient steps to inform themselves adequately about the basic economic facts which existed in an area of economic activity into which they were about to introduce a revised regulatory instrument. In particular, it is agreed by both parties that the respondents never conducted an up to date costs survey to establish what it costs to run a pharmacy in Northern Ireland in 2011. It is also agreed that they never conducted a margins survey to establish the levels of retained profits pharmacists here can achieve- as compared to the profits that may be available in England. Without this core information I consider that the department failed in its basic duty to take reasonable steps to acquaint itself with relevant information and failed in its obligation to equip itself with the information necessary to take an informed decision. The task here was to adjust the English Tariff to conditions in Northern Ireland in a manner which ensured that the statutory purposes of publishing a NI Drugs Tariff would be achieved. Those statutory purposes include ensuring that fair and reasonable remuneration is available for pharmacists here. I cannot see how any Regulator could be satisfied that its proposed regulatory instrument would achieve these purposes when it had not collected the basic economic facts it needed to inform its decisions.

[44] I appreciate that the respondents faced difficulties in collecting the information they needed. Mr Brogan refers in his evidence to the non-cooperation of the applicant with the Department's efforts to conduct a margins survey. In para 32 of his affidavit he says:

> **32. ... It is correct that a margins survey has not been carried out. This is as a result of the lack of consent by the Applicant during the meetings of 15 December 2010, whereby it was made clear that it would challenge the Department/Board if an attempt was made to carry out what it considered to be a 'stand alone' survey and that it would not co-operate until it had agreed the methodology for a 'rolling survey'. Without support from its representative body, the Department and Board were of the opinion that community pharmacists would not comply with a request for information and that an 'enforced' margins survey was not feasible."**

I do not accept this conclusion. The reality was that the department in Northern Ireland, like its counterparts in England and Scotland, had available reserve powers which it might have used to gather the critical information it required to be able to regulate safely in this contentious area. In England and Scotland the equivalent powers had been used years before in order to establish an adequate information

base to regulate safely in those jurisdictions. There was no impediment to the respondents taking equivalent steps in Northern Ireland but they failed to do so and so failed to fill a critical information gap.

[45] At para 34 of his affidavit Mr Brogan asserts that the respondents regarded the applicant's unwillingness to co-operate in a margins survey of a kind it did not like as "an unacceptable form of financial and budgetary veto". It is useful to reflect that a veto can only be exercised if the party subjected to it has no alternative means of achieving its objectives. That was not the situation in the present case. Throughout the relevant time, the respondents held alternative powers through which they could have uncovered the information they needed to inform themselves sufficiently. Their failure to use the tools available to them cannot be laid at the feet of the applicant. On the balance of the evidence I have no doubt that this applicant was less than eager to facilitate discovery of the information the respondents needed. Nevertheless, the responsibility to find out what they need to know rests with the responsible government departments and agencies. In order to discharge this responsibility sufficiently they can and should use whatever tools are available and necessary to access critical information, regardless of the level of co-operation they may receive from any consultee.

[46] The respondents' failure to conduct a costs survey is puzzling. It appears from para 28 of Mr Greene's first affidavit (quoted above) that the Department initially set about taking steps to establish current costs. It held a meeting with the applicant on 23 November 2010 to agree how this would be approached. Yet the very next day it held another meeting at which it announced its decision not to proceed with any survey and to rely instead on old costs data dating from 2005/06.

[47] I do not know why the respondents changed tack in this way. The suggested reason is that they wanted to get an amended Tariff out by the target date of 31st March 2011. It may be that the Department felt it could not collect and collate the necessary costs information before the arrival of that target date and this is why it abandoned the effort to conduct any survey at all. Whether this proposition is correct or not, it is useful for parties in the position of the respondents to reflect carefully about the potential impacts of speed on decision making processes. They should bear in mind that the overriding responsibility of government Departments is to fulfil the statutory objectives set out in the legislation from which they derive their powers. Of course it is essential to fulfil these objectives with all due diligence, including reasonable speed. However, persons in the respondents' position should take care not to pursue speedy decisions at the cost of making under-informed decisions. In most cases short delays in reaching the right result will be preferable to rushing to ill-informed and therefore unsustainable conclusions

(ii) The failure to conduct an RIA

[48] The history of RIAs, as set out by Ms Morelli, shows that they are intended to be useful and constructive tools designed to ensure that all government

interventions of wide impact are fully and appropriately evaluated and considered. Paras 1.6 and 1.7 of the DETI guidance (not referred to in Ms Morelli's affidavit) is in the following terms:

> **'Who is required to do an RIA?**
> **1.6 All government departments and agencies where they exercise statutory powers and make rules with a general effect on others are required by Ministers to produce an RIA.**
>
> **When should I do an RIA?**
> **1.7 .....you must prepare an RIA for all proposals (legislative and non-legislative), which are likely to have a direct or indirect impact (whether benefit or cost) on businesses, charities, social economy enterprises and the voluntary sector.'**

[49] It is hard to see how the guidance could be clearer in relation to the circumstances in which RIAs should be done. There can be no doubt but that the proposed revised Drug Tariff for Northern Ireland was a proposal 'likely to have a direct or indirect impact ... on businesses,' specifically pharmacy businesses, in this jurisdiction. That being so, I consider that the clear terms of the DETI guidance gave rise to a legitimate expectation on the part of the applicant that a RIA would be prepared in this case.

[50] The department maintained that it was not under any obligation to conduct a RIA before introducing the Drug Tariff, *inter alia,* because it is not legislation, did not involve any change in government policy or the introduction of any new system of regulation. The applicant, on the other hand, contended that the department had disregarded these express provisions of the RIA guidance.

[51] In my view the compilation and publication of the Drug Tariff plainly involved the exercise of statutory powers having a general (the applicant would say profound) effect on all pharmacies in Northern Ireland and the communities they serve. The significant policy element involved in the highly contentious Drug Tariff is exemplified by the two judicial reviews and the intensive negotiations which have followed since the introduction of the English/Scottish model.

[52] The measures introduced in the Drug Tariff in the overall context of the financial envelope in my view constituted at least a mechanism capable of delivering or effecting a new or amended policy. As a government department exercising statutory powers and making rules with general effect the department was required by the guidelines to prepare a RIA. This was not done because the department erroneously disregarded the express requirements of 1.6 and 1.7.

[53] The fact that the economic impact of the publication of the Drug Tariff may have been subject to some scrutiny does not absolve the Department from complying with the requirement enshrined in 1.6 and 1.7 of the guidance. Indeed, in light of the various factors adverted to by Mr Greene, particularly in his second affidavit, it might be thought that a RIA would have been particularly appropriate in this case.

[54] The respondent however submitted that even if their submissions on the absence of an obligation to conduct a RIA are rejected that it didn't necessary follow that the failure to conduct such an assessment should result in the condemnation of all or part of the Drug Tariff.

[55] I accept that it does not inexorably follow that breach of the non-statutory requirement to conduct a RIA will vitiate the exercise of the statutory power. However, in light of the protracted background in funding community services in Northern Ireland and the potential impact of the new Drug Tariff on individual pharmacy business and on pharmaceutical services generally in Northern Ireland, disregarding the express requirements of the guidance must be addressed.

[56] The Department has offered no convincing justification for its failure to comply with the guidance and appears to have overlooked or disregarded the requirements of 1.6 and 1.7. The failure to conduct such an assessment constituted the significant procedural flaw in the decision making process. The question then arises whether this flaw was sufficiently serious to render the resulting decision unlawful.

[57] At para 22 of her affidavit Ms Morelli states:

> **"Even if the department is not correct in its view of the requirement for a RIA, it is not accepted that a failure by it to conduct a full RIA was in any way unfair to the applicant, resulted in relevant information being left out of account or otherwise represented a legal basis of challenge to the introduction of the new Drug Tariff."**

[58] Following on from this, she sets out the steps the Department did take to assess the likely impacts of the new Tariff on Northern Irish pharmacists. She says:

> **"As described in earlier affidavits, a high level economic impact assessment was carried out, using the most up to date *English* drug prices which were available."** [Emphasis added]

[59] I consider that this averral illustrates the benefits that a full RIA can bring to the decision making process. The respondents in this case were engaged on the task of generating a Drug Tariff **appropriate to conditions in Northern Ireland,** yet they

were relying on impact assessments derived from English data. Part of the reason for this was that the necessary local data had never been collected (as noted in the previous section of this judgement). However, if an appropriate impact assessment had been conducted it might have provided another opportunity, another avenue for accessing the local **information** that is missing from the picture of the decision making process in this case. It is common case that no RIA was conducted. The absence of a RIA confounds the legitimate expectation of the applicant (founded upon the guidance) that one should have been carried out. The absence of such an assessment may well have resulted in relevant local information being left out of account in this process. I am therefore satisfied that the failure to conduct an appropriate RIA amounted to a procedural irregularity in the process.

The consultation about dispensing fees

[60] Finally there is the question of the consultation about dispensing fees. There is no dispute between the parties that:

(i) The views of the applicant on this issue had been invited and should have been taken into account;

(ii) The applicant had been given until 25 March 2011 to convey its views;

(iii) The decision upon which the applicant was entitled to be consulted was on 24 March 2011, the day before the consultation period accorded to the applicants came to an end.

[61] On the basis of these facts I consider that the respondents breached the requirements of procedural fairness in their conduct of the case. However, I note what Mr Brogan says about the *ex post facto* measures the respondents took to defer the application of this aspect of the amended Drug Tariff until a later date. I accept that it is possible that the respondents did take account of the applicant's views before activating this aspect of the decision it announced on 24 March 2011. I accept that, despite the passage of the formal consultation period, the applicant did make further representations to the respondent about this subject before the relevant changes were brought into force in June 2011.

[62] Nonetheless, the Court has serious concerns about the quality of the consultation that can take place when an official consultation period has expired but before an announced decision has yet been activated.

Conclusion

[63] My three broad overlapping conclusions are as follows:

(i) The respondents failed to carry out sufficient consultation and investigation to enable them to compile and publish a Drug Tariff

which complied with statutory objectives, including the objective of ensuring fair and reasonable remuneration for pharmacists. In particular, they failed to carry out any costs survey or any margins survey, or to use available alternative powers to establish key information about the costs and profits of pharmacy businesses in Northern Ireland.

(ii) The respondents failed to carry out sufficient consultation and investigation to enable them to identify the need for (and arrange for the implementation of) any necessary adjustments to the English Tariff model in light of conditions in Northern Ireland, with the objective of ensuring fair and reasonable remuneration for pharmacists here.

(iii) The Department erred in failing to carry out a Regulatory Impact Assessment (RIA) and in disregarding paras1.6 and 1.7 of the RIA Guidance entitled 'Better Policy Making and Regulatory Impact Assessment: A guide for Northern Ireland'. This error constituted a breach of the applicant's legitimate expectation that a RIA would be conducted in the present case and resulted in the potential loss of relevant information.

[64] Accordingly the judicial review is successful and I will hear the parties, in light of the judgment, as to appropriate relief.