Neutral Citation Number: [2018] EWCA Civ 1925

Case Nos: C1/2017/1596 and C1/2017/1900

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION, ADMINISTRATIVE COURT
Mr Justice Collins
[2017] EWHC 1147 (Admin)

Royal Courts of Justice
Strand, London, WC2A 2LL
Date: 21/08/2018

Before :

LORD JUSTICE IRWIN
LORD JUSTICE HICKINBOTTOM
and
SIR JACK BEATSON

- -

Between :

THE QUEEN (on the application of) **(1) THE PHARMACEUTICAL SERVICES NEGOTIATING COMMITTEE** **(2) SUSAN SHARPE**	Appellants
- and – **THE SECRETARY OF STATE FOR HEALTH**	Respondent
- and – **THE NATIONAL PHARMACY ASSOCIATION**	Interested Party
THE NATIONAL PHARMACY ASSOCIATION	Appellant
-and- **THE SECRETARY OF STATE FOR HEALTH**	Respondent

- -

Alison Foster QC, Saima Hanif and Catherine Dobson (instructed by **Pennington Manches LLP**) for **The Pharmaceutical Services Negotiating Committee** and **Susan Sharpe**
David Lock QC and David Blundell (instructed by **Knights 1759**) for **The National Pharmacy Association**
Sir James Eadie QC and Tom Cleaver (instructed by **The Government Legal Department**) for the **Respondent**

Hearing dates: 22 and 23 May 2018

Introduction

1. This appeal concerns the lawfulness of a package of changes introduced by the Respondent ("the Decision") following an announcement on 20 October 2016 in a document entitled "*Community Planning in 2016/2017 and beyond – Final Package*" ("the Final Package"). Both Appellants are bodies representing pharmacies. The Pharmaceutical Services Negotiating Committee ("PSNC") is the body recognised and tasked, pursuant to statute, with negotiating the Drug Tariff (see below) on behalf of the community pharmacies. The National Pharmacy Association is a trade association, UK-wide and established in 1921, representing around half of NHS community pharmacies.

2. The most important providers of medicines, drugs and appliances prescribed by doctors are the retail pharmacy businesses known as "community pharmacies". In 2015, community pharmacies dispensed over one billion NHS prescription items. Community pharmacies are categorised into small, medium and large by volume of items dispensed. They are also categorised by reference to ownership, as single (owned), chain (owning 2 to 20 pharmacies) and multiple (more than 20 pharmacies). Some pharmacies in multiple ownership are, nevertheless, small and medium pharmacies by dispensing volume.

3. In his judgment, appealed before us, Collins J rejected the challenges of both Appellants. Before this court, the PSNC relies upon six grounds, namely that the judge: (1) ought properly to have concluded that the Secretary of State could not rationally have made the decision on the basis of the information obtained, pursuant to *Secretary of State for Education & Science v Tameside Metropolitan Borough Council* [1977] AC 1014; (2) wrongly concluded that the Secretary of State did not rely on an erroneous estimate of an average pharmacy's operating profit margin of 15%; (3) erred in assessing the significance of the failure to disclose and consult on that supposed operating profit margin; (4) erred in concluding that the non-disclosure did not render the consultation process unlawful, the judge reaching a conclusion inconsistent with his own findings; (5) wrongly discounted and failed to consider a letter addressing the supposed 15% margin, on the basis that the margin had not been relied on; and finally (6) ought to have concluded that the Respondent had unlawfully misused the relevant statutory provisions for the payment of pharmacies to achieve a "fundamental restructuring" of the community pharmacy system, without resort to amendment of primary statute.

4. The NPA supported the case of the PSNC, but also relied upon a discrete ground namely that, in adopting the package of measures in relation to community pharmacies on 20 October 2016, the Secretary of State breached his obligation under section 1C of the National Health Service Act 2006 ("the 2006 Act") to "have regard to the need to reduce inequalities between the people of England with respect to the benefits they can obtain from the health service".

5. This is a judgment of the Court, to which we have all contributed.

Historical Background

6. The following paragraphs are intended to provide context for the Decision and our judgment.

7. Patients need to be able to access drugs and services which have been prescribed for them by NHS healthcare professionals. Consequently, the services to be provided by the Secretary of State as part of the health service include "pharmaceutical services", defined by section 126(8) of the 2006 Act as the provision "to persons who are in England" of drugs, medicines and medical appliances "which are ordered for those persons", as well as "such other services as may be prescribed" and "additional pharmaceutical services provided in accordance with a direction [by the Secretary of State] under section 127".

8. There are over one billion NHS prescriptions made per year. Although some are met by prescribing doctors, the vast majority are fulfilled by privately owned community pharmacies. By regulation 10(2)(a) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (SI 2013 No 349) ("the 2013 Regulations"), made under Part 7 of the 2006 Act, NHS England is required to keep "a list of persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs", i.e. "NHS pharmacists" (see regulation 2).

9. The primary obligation on an NHS pharmacist is to "provide proper and sufficient drugs and appliances to persons presenting prescriptions for drugs and appliances ordered by healthcare professionals in pursuance of their functions in the health service ... " ([4], as expanded by [5-9] and [11-12], of Part 2 of Schedule 4 to the 2013 Regulations). They must also accept and dispose of unwanted drugs, presented to them for disposal ([13-14]).

10. In addition, they have the following obligations:

    i) to give appropriate advice in relation to NHS prescription services [10] of Schedule 4;

    ii) to promote public health messages to members of the public ([16-18]);

    iii) to provide information to users of the NHS pharmacist's pharmacy about other healthcare providers and support organisations [19-20]; and

    iv) to provide advice and support to people caring for themselves or their families, including advice on managing a medical condition [21-22].

    To an extent, these advice-giving services overlap with the primary care services provided by GP practices.

11. Community pharmacies are commercial entities, but they operate under a statutory scheme which has varied the degree of regulatory control from time-to-time. Prior to 1985, the pharmacy market was commercially open, but, following a decline in some areas in the 1960s and 1970s, differential payment arrangements were introduced in the 1980s. In particular, pharmacies with a lower dispensing volume were paid more per item than pharmacies with a higher dispensing volume. That led to a significant expansion in numbers. In the period 1980-85, the number of pharmacies in England and Wales grew by about 130 per year. Furthermore, the new pharmacies tended to cluster round medical surgeries, because of the tendency of patients to get a prescription filled at a pharmacy near a surgery where they had been prescribed medication.

12. The National Health Service (General Medical and Pharmaceutical Services) Amendment (No 2) Regulations 1987 (SI 1987 No 401) introduced measures to regulate the market by imposing a condition that a new pharmacy could only be opened if it was considered "necessary or desirable" to secure adequate provision of pharmaceutical services in a particular neighbourhood (regulation 26(4) of the National Health Service (General Medical and Pharmaceutical Services) Regulations 1974 as inserted by regulation 2(2) of the 1987 Regulations). That stopped the expansion of the market, there being a net increase in the number of pharmacies of only 40 in the decade from 1991.

13. Following concerns expressed by the Office of Fair Trading ("the OFT") in its 2003 report, "The control of entry regulations and retail pharmacy services in the UK", the National Health Service (Pharmaceutical Services) Regulations 2005 (SI 2005 No 641) introduced some limited deregulation, notably by (i) including "reasonable choice" for consumers as a relevant factor in the assessment of applications under the "necessary or desirable" test, and (ii) excepting from the "necessary or desirable" requirement several categories of pharmacy, including those that agreed to open for 100 hours per week. A new pharmacy falling within an exempt category could open on the basis that it was commercially attractive to do so, and it did not have to show that there was a health need for it in the sense that it was "necessary or desirable" for securing adequate provision for their neighbourhood.

14. That led to a fresh expansion in the number of pharmacies, but (i) the majority applied under an exemption, only 25% of new pharmacies applying under the (relaxed) "necessary or desirable" test; (ii) nearly 80% of new pharmacies opened less than 1km (later 1 mile) away from another pharmacy, compounding the clustering phenomenon; and (iii) this influx of new pharmacies did not result in any rise in the rate of pharmacy exit from the market. This resulted in the conclusions expressed by the OFT in its 2010 report, "Evaluating the impact of the 2003 OFT study on the control of entry regulations in the retail pharmacy market", stating (at [4.24]):

> "Overall, this evidence suggests that an effect of the reforms has been to facilitate entry in areas already well served by pharmacies."

Those areas were generally urban.

15. Three of the four exemptions from the "necessary or desirable" criterion, including the 100 hours pharmacies, were abolished in 2012 (by the National Health Service (Pharmaceutical Services) Regulations 2012 (SI 2012 No 1909)). As a result, the rate of increase in numbers of pharmacies has dramatically slowed, from a net increase of over 250 per year before 2012, to 14 in 2015-16.

16. Ms Jeannette Howe is the Head of Pharmacy in the Medicines and Pharmacy Directorate of the Department of Health. In [83] of her statement dated 1 February 2017, she explains that, as a result of these developments, areas of greater deprivation have been disproportionately well-funded from the community pharmacy budget. By way of example, 17% of funding goes to pharmacies in the most deprived decile (where 59% of the pharmacies are in a cluster), and 5% goes to the pharmacies in the least deprived decile (where only 9% of the pharmacies are in a cluster).

17. However there is also evidence – which appears to be uncontroversial, and which we accept – that now in areas of multiple deprivation, (i) there is a relative scarcity of NHS GPs, i.e. there are fewer GPs per head of population than elsewhere; (ii) residents are less likely to attend their GP promptly or at all; and (iii) there are proportionately higher levels of community pharmacies, often in clusters. Consequently, in such areas, there is generally more reliance on community pharmacies to give medical advice and support, as well as meet prescriptions.

The Statutory Provisions

18. The statutory provisions governing the Drug Tariff are complex. For convenience, we have placed them in Annex 1 to this judgment.

19. In summary, the National Health Service Commissioning Board ("the Board") and the Secretary of State have concurrent duties to provide for the service required under the 2006 Act, as amended by the Health and Social Care Act 2012 ("the 2012 Act") (s.126, 2006 Act). The relevant service here is the provision of "proper and efficient drugs and medicines and listed appliances" for the Health Service in England (s.126, 2006 Act). They are referred to as "pharmaceutical services" (s.126(8), 2006 Act).

20. Remuneration is dealt with in ss.164 and 165 of the 2006 Act. The "determining authority" for this Decision was the Secretary of State (s.164(6) to (10) of the 2006 Act). By s.165(1)(a), the Secretary of State was obliged to "consult a body appearing to him to be representative of persons to whose remuneration the determination would relate". It is agreed that meant the PSNC. The Secretary of State was empowered to consult others as he thought fit (s.165(1)(b)). By s.165(9): "Any determination may be made only after taking into account all the matters which are considered to be relevant by the determining authority".

21. By s.127(A) of the 2006 Act, the Secretary of State must publish in the Drug Tariff all directions he has given pursuant to s.127. Regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 provides that the Drug Tariff is the aggregate of such determinations or directions. The Drug Tariff may be amended at intervals as the Secretary of State thinks fit, but amendments must be published in a consolidated version.

22. The statutory provisions bearing on the appeal by the NPA are addressed later in this judgment.

The Build-up to the Decision

23. We analyse below the two critical documents which were before the Secretary of State at the time of his decision. However, it is of importance to Grounds 1 to 5, to establish what transpired before those documents reached final form. We therefore include a close review of the documentary record. The judge addressed these matters in [15] and following. The chronology appears to be as follows.

24. There is no evidence, so far as the judge found or emerges from the material before us, as to when it was first decided that major reductions in the cost of pharmacy services would be required. However, it seems clear that such a policy was being developed by at least the middle of 2015.

25. In July 2015, internal documents considering pharmacy profitability anticipated that "some smaller/less profitable pharmacies [are] likely to close". On 24 July 2015 there took place the meeting in the Department with an "industry insider", who gave the view that a "typical pharmacy operates at around 10% operating profits". This meeting was conducted on the basis that the "insider" could not be quoted or identified. The information provided and notes made at this meeting were destroyed at the request of the "insider". The meeting was only disclosed as a result of these proceedings.

26. On 4 September 2015, a submission to the Minister included the following:

> "1. In July we presented options for reforming the community pharmacy system in England. You asked us to develop a proposal that would:
>
> - Not require any changes to primary legislation
> - Reduce spend on the Community Pharmacy Contractual Framework by £400m by 2017/18.
> - Protect vulnerable pharmacies which are essential for maintaining patient access e.g. in rural areas.
>
> **Recommendations**
>
> 2. Should you decide to proceed, we recommend that
>
> - You give a steer on which option for protecting vulnerable pharmacies you prefer (see para 9 below).
> - We start negotiations soon with the Pharmaceutical Services Negotiating Committee (PSNC) [REDACTED] based on realising savings of £400m by 2017/18 [REDACTED] against NHS England's internal spending projections. We present our proposals as at Annex 1 but allow PSNC to suggest alternative ways of delivering the required savings.
>
> ...
>
> 6. We see these proposals as achieving a sensible balance between the certainty of efficiency savings, the management of stakeholder reaction and supporting strategic change. They will move pharmacy's focus from the supply function more towards clinical activity, promote more effective and efficient use of medicines and, over time, empower local commissioning teams to integrate pharmacy more fully within primary care services. In the presentation of these funding reforms it will be important to highlight the transformational opportunity for pharmacy these measures will represent.
>
> ...

The impact on the community pharmacy sector

9. We should not underestimate how strong the resistance and campaigning will be to what are real, cash cuts that will inevitably – no matter how we distribute them – reduce the profits and the value of many businesses and put some pharmacies out of business. We cannot guarantee there won't be "save our local pharmacy" campaigns. But we must remember that there are an estimated 25% too many pharmacies so some level of closures would not necessarily be a bad thing.

10. We have included two options for protecting vulnerable pharmacies....

...

Negotiations with the PSNC

12. These reforms are likely to be received very negatively by the pharmacy sector given the level of the funding reduction. Normally negotiations with the PSNC are concluded with an agreement, but it is likely we would need to impose this funding cut, which would be unprecedented. There is a strong possibility of a media and public backlash if local pharmacies are forced out of business as a result. We will need to reassure the sector the increased funding for local pharmacy services in primary care, that is influenced and prioritised locally, and aligned with new care models, is in some way ring fenced. Careful political handling will be essential.

13. When considering our negotiating position it will be important to provide community pharmacies, as commercial organisations, with certainty over the level of funding they can expect over the coming years...

14. We would need to move very quickly to start realising savings from 2016/17. The statutory requirement for making changes to the pharmaceutical services funding is to consult with the Pharmaceutical Services Negotiation Committee, but there is a legitimate expectation that we do this through a negotiated process ..."

27. In the relevant Annex to the submissions, those advising consider in more detail the impact of the preferred changes. The analysis included an attempt to identify the impact by pharmacy type, by looking at the income reduction and access impact in the Birmingham area, in a section focussed on the "impact of NHS remuneration funding on profitability in community pharmacy" (*sic*). This part of the advice reads:

> "32. The profitability of a pharmacy business will largely depend on a combination of the volume of NHS prescriptions dispensed and thus payments earned, the margin being made on drug

purchases and the margins being made on over the counter (OTC) and retail products. Running costs are fairly stable, as pharmaceutical regulation is clear about minimum staffing and safety levels. The costs of debt, used to purchase a NHS pharmacy and/or premises from which to operate, will vary significantly across businesses.

33. Community pharmacy is seen as a "steady earner" as a business proposition, with a "highly secure income" due to the steadily increasing demand for prescriptions, the relatively stable and generous remuneration payments in place and the ability to use NHS prescription services as an opportunity to cross-sell prescription items. With restricted control of market entry, pharmacy businesses retain significant "goodwill" value and can exchange hands for over £1m per pharmacy.

34. The extent to which we can know precisely these costs, margins and the profitability is limited to:

- NHS data about the level of NHS payments made
- Information we can glean from Companies House data
- Informal conversations with industry insiders

35. We cannot access the following data that would enable us to have a much richer picture:

- The level of margin being earned on OTC/retail products
- The level of additional margin on drug purchasing enjoyed by large multiples – so far they have refused to provide meaningful data that would allow us to understand this.
- The costs incurred by individual pharmacies on NHS activity in particular
- Revenue and profits earned on non-NHS business

36. There are a number of business models and organisational types of pharmacies. Any changes to the CPCF and the remuneration system will have a differential impact on pharmacies depending on the size of the company it is part of and its business model, as well as the volume of NHS prescriptions it dispenses. For the purposes of our analysis we have looked at the impacts of the proposed changes on different sized pharmacies and also according to company type. Table 7 overleaf shows the distribution of pharmacies amongst those nine groupings of size and company group. Taken together with

the analysis that follows, this gives a sense of the scale of the impact across different parts of the sector.

...

37. The analysis below, of the impacts of a reduction in NHS funding on pharmacy profitability by pharmacy type, is therefore limited. Any conclusions and decisions will be informed by judgement as much as clear evidence.

...

43. Individual, independent pharmacies (where there is only one pharmacy in the company) are making a lower margin on drug purchases, have a relatively fixed cost base and cannot spread cost across a wider business group and diversify their sources on income. 3,683 of pharmacies are independent – this is just under a third of pharmacies in England. As such they are the most vulnerable to reductions in NHS income. Significant levels of debt would increase this pressure.

44. This risk might be mitigated by higher levels of non-NHS sales in individual pharmacies.

Research on operating profit using Companies House data

45. As part of this commission we have examined Companies House data from 79 companies in [an] attempt to calculate profitability levels in the pharmacy sector. We have divided them into nine taxonomy types and calculated their operating profit margin and the average operating profit by the number of pharmacies in the company.

46. Tables 8 and 9 below summarises the findings. As can be seen from the table, there is wide variation in profitability across pharmacies we could find accounts for, and the relatively small sample size means there is considerable uncertainty around these numbers.

...

47. This analysis is clearly limited by the small sample size and the representativeness of the sample. Most independent small pharmacies are sole proprietors are (*sic*) thus are not incorporated as legal entities. Even those small pharmacies that are incorporated as companies do not need to report detailed accounts unless they have a turnover of £6.5m or more. The small pharmacies in our dataset are voluntarily reporting detailed accounts, and typically pharmacies choose to do this if they are seeking a buyout or equity investment, thus making them unrepresentative of other small pharmacies. Many small

> pharmacies, while report accounts separately, have group purchasing arrangements with larger chains or management relationships with other firms which further confounds the data available."

28. Tables 8 and 9 are of significance, since they were the basis of the estimate, subsequently repeated and heavily challenged by the Appellants, that broadly community pharmacies yielded a 10-15% operating profit margin. The Tables are reproduced in Annex 2 to this judgment. It will be seen that there are very wide variations in the profit margins revealed by the accounts analysed.

29. In early September 2015, a draft of the "Duties Document" referred to a 20% increase in pharmacy numbers between 2003 and 2015, and stated there was "over-provision in some areas". A ministerial submission on the proposals for consultation referred to an "estimated 25% too many pharmacies". On 7 September an internal presentation anticipated that some pharmacies would close as a result of the changes proposed.

30. In the course of a meeting between Department of Health, NHS England and the Company Chemists Association, minutes record the view expressed by one contributor that there were "perhaps 3000 too many pharmacies". On 22 October 2015, an internal presentation within the Department of Health referred to a 10-15% operating margin and considered numbers of pharmacies which might close under different funding proposals.

31. On 6 November 2015, a submission was made to the Minister. According to the second witness statement of Ms Howe (page 34), this was the "first occasion on which Ministers were formally asked to determine the funding settlement for 2016/2017". Approval was sought for a savings target of £300 million. The submission included consultation proposals and referred to a 10-15% operating margin and a modelling of up to 2000 pharmacies "becoming unviable". A further iteration of the draft Duties Document again included reference to the 10-15% operating margin and appears to have made the assumption that some pharmacies would close with modelling of different figures. On 9 November 2015, similar figures were included in an internal departmental presentation.

32. On 10 November 2015, there was a meeting between the Minister, Department of Health officials and the PSNC. The PSNC witness Ms Sharpe suggests the Minister indicated that the closure of several hundred pharmacies would be "insufficient". This is in dispute as a matter of fact.

33. On 20 November 2015, a further ministerial submission gave an estimate of pharmacy closures being "as many as 2060".

34. On 17 December 2015, the formal beginning of consultation was announced. The Department announced that funding for community pharmacies would be reduced from £2.8bn in 2015/16 to £2.63bn in 2016/17, with the changes due to take effect in October 2016. This proposal went by letter to PSNC. On 31 December 2015, a departmental letter to the PSNC provided further information.

35. In January 2016, there were meetings between the Department and PSNC in the course of which PSNC requested sight of the analysis of the impact of the proposals. On 13

January 2016, the Parliamentary All-Party Pharmacy Group met with the Minister. In response to questioning, the Minister emphasised that the Government "feels the market can withstand such change". He indicated that closures could be between 1000 and 3000.

36. In January to March 2016, the PSNC made a number of requests to see any analysis or modelling relied on as to the impact of pharmacy businesses. On 28 January they were told that the Department had "access only to information that is already in the public domain (Companies House data)". At a meeting on 2 March 2016, the Department was asked if they had modelling as to the number of closures likely to arise. The answer was that:

> "... the viability of each individual pharmacy is unclear, and the intent is to focus on those that are most needy and whose closure would impact most on local populations. However it is difficult to assess viability and the end measure is likely to have an inevitable degree of crudeness, targeting those who would be most missed.
>
> MD queried if modelling has suggested 3,000 likely closures, or if the number DH would wish to save was c. 1,500. DP noted the complexity in that one closure can increase the viability of another (sic) pharmacies. This is why estimating of closures has been avoided. ..."

37. A later draft of the Duties Document from 22 June 2016, recognised that the removal of the establishment payment would impact "differently on different types of contractors" and particularly on the "small (low prescription volume) pharmacies". The phasing of the reduction in that payment was designed to "minimise the disproportionate impact of these funding reductions on low prescription pharmacies".

38. This document went on to consider "pharmacy viability" and emphasised the difficulty of predicting the impact:

> "37. Overall, pharmacies would see a cut of 6.1% on average in remuneration in 2016/17 (equivalent to 12.1% in the second half of 2016/17) and 7.4% in 2017/18. It is difficult to predict the impact of these proposals on the viability of pharmacies and, therefore, which pharmacies might close as a result of the cut in funding. For pharmacies that do not qualify for the Pharmacy Access Scheme (PhAS), this reduction is equivalent to 6.6% on average in remuneration in 2016/17 (equivalent to 13.3% in the second half of 16/17) and 8.3% in 2017/18. These numbers assume that all pharmacies receive the quality payment. However, our analysis suggests pharmacies run a 15% operating margin, that is, the margin before tax and interest is charged. Thus with a 12% reduction in revenue on average, we can assume some pharmacies will be at risk of closure. Independent and chain pharmacies would be at high risk of closure, but even multiples may choose to close pharmacies that do not bring in significant footfall.

...

> 41. The figures should therefore be treated as indicative only, and overall this analysis is testament to how difficult it is to predict how pharmacies might be affected as a result of these proposals."

39. On 2 August 2016, the Secretary of State wrote to the Prime Minister concerning these changes. Collins J dealt with this letter as follows:

> "30. ... A closure figure of between 500 and 900 was said to result from the latest draft impact assessment. That assessment has not been disclosed."

The Decision

40. The foregoing is the background to the decision announced on 20 October 2016 (the Final Package), which comprised the following elements:

i) A reduction in the overall amount of funding for pharmacies from £2.8bn for 2015-16 to £2.687bn for 2016-17 and £2.592bn for 2017-18. This reduction in the funding for pharmacies was agreed between the Secretary of State and HM Treasury, and is not the subject of any challenge.

ii) The consolidation of four different fees previously paid to pharmacies for different activities into a single activity fee, paid in proportion to the number of prescription items dispensed.

iii) Phased reductions in the fixed sum "establishment payment".

iv) The introduction of the Pharmacy Access Scheme ("PhAS"), which in certain circumstances gives additional support to a pharmacy where there was no other pharmacy within one mile.

v) The introduction of a quality-based payment to reward pharmacies which meet particular quality standards.

41. By way of explanation:

i) Throughout the period covered by the decision, the overall budget for NHS England was to increase year-on-year. As the Impact Assessment (see below) made clear, the reduction in the funding for pharmacies was part of a wider funding reallocation within the NHS, whereby the funds made available from the reduction for pharmacies were to be allocated to other parts of the NHS where the need was considered greater.

ii) In addition to reducing the overall budget for community pharmacies, the decision involved the reduction of fixed payment elements in favour of per item elements, with the intention of giving market forces a greater part to play. It was envisaged that this could result in a reduction in the number of pharmacies. It is important to note that the proposed budget was fixed, in the sense that, if the number of pharmacies was reduced, then any money that would otherwise

have gone to pharmacies which closed, would be redistributed to those that remained open, in (for example) higher per item rates. Hence, the Respondent could not "gain" from the closure of pharmacies.

42. As we have indicated, two critical documents covering the anticipated impact of the proposals, drafted by officials, were before the Secretary of State when he considered the decision. The first was the final version of the Impact Assessment dated 19 October 2016, which tested the assumption that "there will be no significant impact on patient health, and that patients will continue to receive the pharmacy services they need". At [21], it was noted that "evidence shows that deprived areas (by the Index of Multiple Deprivation) tend to have more clustering of pharmacies, and [we] have considered whether deprived areas could be adversely affected by this policy as a result". It noted that, for the historical reasons to which we have referred, "it is not necessarily the case that pharmacies cluster around deprived communities to meet an increased need"; and, it said, "typically, access [to a pharmacy] is not at risk in areas with high provision".

43. The Impact Assessment included the following assessment:

> "54. It is difficult to predict precisely the impact of these proposals on the viability of community pharmacies and, therefore, which - if any - might close as a result of the cut in funding. Our indicative analysis suggests community pharmacies run a 15% operating margin, that is, the margin before tax and interest is charged. This analysis uses the limited data available. We have matched with our payments data with Companies House data for 80 chains and multiples. This data and analysis may not be representative of the full population of pharmacies. Nevertheless, a funding reduction of 12% in 16/17, could mean that some community pharmacies would be at risk of closure, without adapting their business. In a scenario where closures did occur, independent (typically micro business) and chain pharmacies could be at higher risk of closure, but even multiples may choose to close community pharmacies that do not bring in significant footfall. As stated above though, there is no reliable way of estimating closures, and the potential impacts in this IA are assessed on the basis that there is a scenario where no pharmacy closes.
>
> 55. Moreover, it is not clear, if the viability of an individual business is threatened, whether these businesses will close or simply be taken over by other owners on the basis that they can be run more efficiently and remain viable business propositions. For example, a current pharmacy may become unviable because it is unable to meet the quality criteria in order to benefit from payments from the Quality Scheme. Another owner may be able to run the business in such a way so as to benefit from those payments, and/or simply run the business more efficiently.
>
> 56. Finally, there is an important interdependency in that, if a pharmacy closes, it is likely that the prescriptions that were dispensed by that pharmacy would be redistributed to

> pharmacies located nearby. Therefore, pharmacy closures, if any were to occur and as is currently the case, would have an immediate positive impact on the viability of remaining pharmacies.
>
> 57. For these reasons, it is impossible to provide any robust estimate of the number of pharmacy closures that may result. However, **hypothetical closure scenarios** are examined in the sensitivities section below to illustrate the scale of the impact on patient travel times, were pharmacies to close."

44. The second critical document was the final version of the Duties Document, in which the Secretary of State's various statutory duties were considered.

45. The Duties Document recited a history of the consultation process with interested parties, including the PSNC, indicating that the original package of changes had been revised, including reduction in the level of savings sought in 2016/17, in recognition of the time taken to reach a decision and the need to give "reasonable notice" of funding reductions. The implementation date was delayed from October 2016 to December 2016. The PhAS package was "enhanced". The PSNC had "rejected the revised package on 13 October 2016". The document summarised counter proposals put forward by the PSNC.

46. The Duties Document went on to consider the impact of the changes on community pharmacies, under the heading "Pharmacy Viability". The following extended passage from the document is critical for the Decision, encapsulating the view that the impact of the proposed changes on pharmacies was unpredictable:

> "38. Various respondents to our consultation expressed their concern that pharmacies could close as a result of the funding reductions. There was a particular concern about the impact on smaller, independent pharmacies, including in inner cities. We also heard specific representation from 100 hours per week pharmacies that they could become unviable as a result of the funding reductions, and that the 100 hours per week pharmacy model is, in their view, not sustainable in the long term.
>
> 39. Reducing income would mean that community pharmacies must reduce their costs, change their business model or accept reduced profits, and in some circumstances this could mean pharmacies become economically unviable. However, for the reasons outlined below, this is not possible to predict.
>
> 40. There is no reliable way of estimating the number of pharmacies that may close as a result of this policy, and the potential impacts in this Impact Assessment are assessed on the basis that there is a scenario where no pharmacy closes.
>
> 41. There are a number of business models within the community pharmacy sector, and reductions in NHS funding

will impact differently on different community pharmacies depending on a range of factors, such as:

- The type of company the community pharmacy is part of (e.g. independent, chain or multiple),
- The volume of NHS prescriptions it dispenses,
- The pharmacy's business model (e.g. whether it has a large retail arm or is predominantly focused on delivering services commissioned by NHS England, CCGs and/or local authorities) and its level of income from other sources – this could be both from retail and other private streams, but also from being commissioned to provide services with funding from other sources;
- The costs of the debt used to purchase an NHS community pharmacy and other overheads, such as lease costs; and
- The way the business is financed.

42. Overall, community pharmacies would see a cut of 4.0% on average in remuneration in 2016/17 and 7.4% in 2017/18 compared to 2015/16. For community pharmacies that do not qualify for the PhAS, this reduction is equivalent to 4.6% on average in remuneration in 2016/17 and 8.3% in 2017/18. For pharmacies not receiving the PhAS or the quality payment, the average reduction in remuneration is 10.9% in 2017/18 (the quality payment is first introduced in 2017/18). These numbers assume that all community pharmacies receive an equal share of the quality payment.

43. It is difficult to predict precisely the impact of these proposals on the viability of community pharmacies and, therefore, which – if any – might close as a result of the cut in funding. Our indicative analysis suggests community pharmacies run a 15% operating margin, that is, the margin before tax and interest is charged. This analysis uses the limited data available. We have matched with our payments data with Companies House data for 80 chains and multiples. This data and analysis may not be representative of the full population of pharmacies. Nevertheless, a monthly revenue reduction of 12% on average in 2016/17 could mean that some community pharmacies would be at risk of closure, without adapting their business. In a scenario where closures did occur, independents (typically micro business) and chain pharmacies could be at higher risk of closure, but even multiples may choose to close community pharmacies that do not bring in significant footfall. As stated above though, there is no reliable way of estimating

> closures, and the potential impacts in this IA are assessed on the basis that there is a scenario where no pharmacy closes.
>
> 44. Moreover, it is not clear, if the viability of an individual business is threatened, whether these businesses will close or simply be taken over by other owners on the basis that they can be run more efficiently and remain viable business propositions. For example, a current pharmacy may become unviable because it is unable to meet the quality criteria in order to benefit from payments from the quality scheme. Another owner may be able to run the business in such a way so as to benefit from those payments, and/or simply run the business more efficiently.
>
> 45. Finally, there is an important interdependency in that, if a pharmacy closes, it is likely that the prescriptions that were dispensed by that pharmacy are redistributed to pharmacies located nearby. Therefore pharmacy closures will have an immediate positive impact on the viability of remaining pharmacies.
>
> 46. For these reasons, it is impossible to provide any robust estimate of the number of pharmacy closures that may result. However, hypothetical closure scenarios are considered in the Impact Assessment..."

47. The Duties Document went on to consider access to pharmacies, in the context of what was said to be the unpredictable outcome so far as closures were concerned. Consideration of impact led into consideration of the PhAS, as the device to ensure acceptable access, if closures threatened significant diminution of pharmacies within a convenient travel distance.

48. Under the heading "Duty as to reducing inequalities (section 1C NHS Act 2006)", the Duties Document continued as follows:

> "163. When exercising his functions in relation to the NHS, the Secretary of State must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS.
>
> 164. It is important to emphasise that this duty is separate from the PSED [i.e. "the public sector equality duty" imposed upon public authorities by section 149 of the Equality Act 2010 to "have due regard to the need to... eliminate discrimination" etc], and is about a need to reduce inequalities that may or may not be based on protected characteristics. Socio-economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation.
>
> 165. Currently, there is ready access to pharmacies, with 89.2% of the population able to get to one within 20 minutes by walking (recognising that some people have mobility

difficulties, which means that these statistics may not be directly relevant). Furthermore, it should be noted that access is greater in areas of highest deprivation.

166. That said, inevitably there are concerns, to which our mitigations respond, that if profitability of pharmacy contractors is affected, this will have a disproportionate detrimental impact on less affluent areas or on areas where there might inevitably be less choice because of demographic factors. The potential for impact on transient populations needs also to be considered.

167. A consequence of reduced funding of the order proposed would be the increased likelihood of pharmacies only being open their minimum hours or withdrawing from provision of NHS pharmaceutical services altogether. The surplus capacity of pharmacies in some areas and possibility of closures, together with a more general survey of impacts, are discussed above.

168. Overall the PhAS is expected to mitigate the impact of any potential pharmacy closures in isolated areas and areas where pharmacy provision is sparse relative to other areas. We do not consider that the proposals will have any significant impact on health inequalities and we expect that in fact the PhAS and other proposals (such as the PhIF) will result in pharmacy funding being better focused on areas where there is most need for it. To ensure that no area is adversely affected, a review of eligibility will be granted for pharmacies that may have narrowly missed out on the scheme through the distance criteria, but are in areas of high deprivation and are crucial to patent access.

Impact on deprived areas

169. The pharmacies included in the PhAS include those pharmacies that are relatively isolated, and serve populations that are both in areas with relatively sparse provision of pharmacies, and higher needs levels. We have ensured this by cross checking eligible pharmacies against our composite index, which is a measure of the pharmacies that are most important for maintaining patient access.

170. To consider this further, we looked at some of the examples of communities highlighted in "Dispensing Health Equality". The qualification criteria – that pharmacies that are more than a mile from another pharmacy to qualify – makes it very likely that pharmacies in rural areas such as Teignmouth, mentioned in this report, will qualify.

171. We are also aware of preliminary research by Adam Todd of Durham University, which shows that deprived areas (by the Index of Multiple Deprivation) tend to have more clustering of pharmacies, and have considered whether deprived areas could

> be adversely affected by this policy as a result. However, it is also worth noting that it is not necessarily the case that pharmacies cluster around deprived communities to meet an increased health need – the correlation may be because deprived communities tend to be in urban, built-up areas. This suggests some pharmacies may operate in these deprived communities to benefit from the higher footfall and would continue to be viable without PhAS payments.
>
> 172. The PhAS does not offer protection to pharmacies that are in clusters. This is because the PhAS is designed to tackle the issue of 'access': should a pharmacy in a cluster close then this would be far less likely to have a material impact on patient access.
>
> 173. Irrespective of the reasons for this clustering, the PhAS is more likely to benefit rural, sparsely populated areas than built up, urban areas. Generally this first type of area will be less deprived than the latter which means there may be a disproportionate effect on deprived communities were any closures to occur.
>
> 174. We have, however, ensured the pharmacies deemed the most essential for patient access are protected by the PhAS, by cross-referencing the list of eligible pharmacies with the composite index developed during the design phase – this incorporates the index of multiple deprivation. In addition, to ensure that no area is adversely affected, a review of eligibility will be granted for pharmacies that may have narrowly missed out on the scheme through distance criteria, but are in areas of high deprivation and are critical to patient access. Reviews will be granted were (sic) the pharmacy is located in the top 20% most deprived areas, and are 0.8 miles away from another pharmacy. To be successful, a pharmacy will also have to demonstrate that it is critical for access."

49. Following the Decision, the Minister presented the package of changes to Parliament in a statement made on the morning of 20 October 2016. He gave no estimate of the number of closures in the course of the statement itself, although it was clearly implicit that there would be an impact arising from the reductions in funding; indeed, the PhAS was expressly introduced as protecting pharmacies from that impact in the eligible areas, to preserve acceptable access.

50. In response to a question as to the number of pharmacies which would close, the Minister did say:

> "I do not know. It is possible that none will close. I believe that 3,000 will close. However, I would say this. The average operating margin that the pharmacy makes on the numbers that I quoted earlier is 15%. That is after salaries and rent. The cuts that we are making, or the efficiencies that we are asking for, are

> significantly lower than that. Of course there is no such thing as an average pharmacy, which is why I cannot guarantee that there will be no changes. What I can say is that, if there are mergers and if there is some consolidation, that demand does not go away – it goes to the other pharmacies in the cluster. To say that those pharmacies will be put under more pressure is plain wrong."

51. On 3 November 2015, the Appellants wrote to the Department challenging the 15% figure and its basis. Ms Howe replied on behalf of the Department on the following day, in the following terms:

> "One of the questions you raised was in respect to the 15% operating margin referenced in the Oral Statement to Parliament. I undertook to provide further information. The next day, I emailed and directed you to paragraph 54 of the Impact Assessment, which describes how the 15% operating margin was derived. On 24th October you requested a list of the companies and the date of the accounts, so that the PSNC could replicate and check the figure.
>
> In this period the Department has needed to prioritise the actions to implement the reforms from 1st December 2016. It has also needed to handle parliamentary business, such as the Opposition Debate on Wednesday, as I indicated in my email. At no point has the Department refused to provide the information on the 15% operating margin.
>
> To seek to assess the operating margin of community pharmacies the Department accessed information available publicly, namely data held by Companies House. Rather than merely providing you the list of companies and year of their accounts, I enclose more detailed information provided by our economists on how the indicative figure of 15% operating margin was derived, to assist the PSNC in understanding the Department's analysis.
>
> In providing this information, it is important I correct a claim made in your letter. While this indicative analysis of the operating margin was contained within the Impact Assessment and formed part of the data which informed Ministers' decision, it would not be right to say it was fundamental to Ministers' decision as you suggest. Ministers took into account a range of factors."

52. Essentially, at this point the dispute between the parties crystallised.

Evidence of Actual (as Opposed to Anticipated) Impact

53. The evidence is that there were 11,688 pharmacies in 2015-16. There is no evidence as to how many pharmacies have closed during the 18 months period since the decision began to be implemented, although Sir James Eadie for the Secretary of State said, on

instructions, that the net reduction in the number of pharmacies was in the region of 120.

54. However, the impact may not be restricted to closures. It may extend to a reduction of services. Mr Lock QC for the NPA relies on evidence from two pharmacists, who own pharmacies in deprived areas, as to the effect of the decision on them. Ms Nazneen Khideja opened "A Karim's Chuckery Pharmacy" in Walsall in 2012, under the 100-hour exemption. In her statement of 10 January 2017, she states that dispensing NHS prescriptions is only a relatively small part of the services her pharmacy provides; and she considers the wide range of primary healthcare services she provides to patients to be vital in an area where there are no easily accessible GP practices [30]. She says that the assumption that the range of services will continue to be provided even if pharmacies close is "frankly ludicrous". Patients are reluctant to travel to seek advice about their health. She considers that, if her pharmacy were to close, then it seems inevitable that many patients would stop having the benefit of health advice at all. The second pharmacist witness, Nicholas Jephson, with a shop in Swindon, says in his statement dated 16 February 2017 that, rather than close his pharmacy altogether, he has effectively cut the services he provides. He has restricted his minor ailment patients to the 25 people he is contracted to see (referring others to a local GP) [15], he has ceased the free prescription delivery service [17-20], and he has begun to charge £250 per year for a dosette box service [21-24]. Reduced levels of service to patients, he considers, are inevitable [30].

Ground 1: The *Tameside* Issue

55. The parties are agreed as to the legal test here. The duty of sufficient enquiry is subject to a *Wednesbury* challenge only. As Laws LJ put it in *R (Khatun) v Newham LBC* [2005] QB 37; "it is for the decision-maker and not the Court to conclude what is relevant" and "to decide upon the manner and intensity of inquiry to be undertaken" [17]. This formulation is echoed in the language of s.165(9) of the 2006 Act quoted above.

56. The Respondent emphasises the following passage from the judgment of the Divisional Court in *R (Plantagenet Alliance Ltd) v Secretary of State for Justice & Others* [2014] EWHC 1662 (Admin) at [100].

> "100. The following principles can be gleaned from the authorities:
>
> (1) The obligation upon the decision-maker is only to take such steps to inform himself as are reasonable.
>
> (2) Subject to a *Wednesbury* challenge, it is for the public body, and not the court to decide upon the manner and intensity of inquiry to be undertaken (*R(Khatun) v Newham LBC* [2005] QB 37 at paragraph [35], per Laws LJ).
>
> (3) The court should not intervene merely because it considers that further inquiries would have been sensible or desirable. It should intervene only if no reasonable authority could have been satisfied on the basis of the inquiries made that it possessed the

> information necessary for its decision (*per* Neill LJ in *R (Bayani) v. Kensington and Chelsea Royal LBC* (1990) 22 HLR 406).
>
> (4) The court should establish what material was before the authority and should only strike down a decision by the authority not to make further inquiries if no reasonable council possessed of that material could suppose that the inquiries they had made were sufficient (*per* Schiemann J in *R (Costello) v Nottingham City Council* (1989) 21 HLR 301; cited with approval by Laws LJ in (*R(Khatun) v Newham LBC (supra)* at paragraph [35]).
>
> (5) The principle that the decision-maker must call his own attention to considerations relevant to his decision, a duty which in practice may require him to consult outside bodies with a particular knowledge or involvement in the case, does not spring from a duty of procedural fairness to the applicant, but from the Secretary of State's duty so to inform himself as to arrive at a rational conclusion (*per* Laws LJ in *(R (London Borough of Southwark) v Secretary of State for Education (supra)* at page 323D).
>
> (6) The wider the discretion conferred on the Secretary of State, the more important it must be that he has all relevant material to enable him properly to exercise it *(R (Venables) v Secretary of State for the Home Department* [1998] AC 407 at 466G)."

57. The Respondent also relies on the approach to the *Wednesbury* test in the field of healthcare policy decision-making set out in the judgment of Green J in *R (Justice in Health Limited) v Secretary of State for Health* [2016] EWHC 2338 (Admin) at [186]:

> "186. In determining whether a decision maker has acted irrationally the intensity of the scrutiny to be applied by a Court is context sensitive. Case law tends to suggest that the following considerations will tend to broaden the scope of the margin of appreciation: where the decision maker is taking a decision in the health field with the objective of improving patient care; where the decision adopted is prospective and precautionary (ie based upon a prediction of future benefit and where there is perceived to be a benefit in acting sooner rather than later notwithstanding uncertainties); where the decision maker has indicated a willingness and intention to review the policy as it unfolds to ensure that it is in fact working adequately and to review and modify it to address emerging problems. "

58. It is also relevant to re-emphasise, in relation to this Ground and indeed overall, that there is and can be no challenge to the "high-level policy decision" that there had to be efficiency savings in the funding of pharmaceutical services. Ms Foster QC for the PSNC was most clear on the point. Her challenge was not to the decision that savings were necessary, but rather to the means by which the savings were achieved, both procedurally and in the detail of the eventual decision.

59. The Appellants submit that it was material to the *Tameside* duty that (1) the decision as to pharmacy remuneration had to be considered in the context of the overarching duties under ss.1-1C of the 2006 Act, and in particular the duty to "secure ... continuous improvement" in the quality of NHS services, under s.1A, (2) that "in order to use the Drug Tariff to comply with the overarching duties and to achieve the SoS's stated objectives, the SoS had to obtain reliable and cogent information as to how the market would respond to the proposed cuts, the economic viability of pharmacies, and the likely level of closures", and (3) that any cost-benefit analysis "had properly to assess the impact of the cuts on other parts of the NHS".

60. The Appellants go on to submit that –

> "... there is no dispute ... the enquiries were limited to obtaining two sources: (1) one informal secret conversation with one "industrial insider" and (2) ... consideration of one set of yearly accounts for 52 pharmacies – out of approximately 11,600 – obtained from Companies House."

In this way, the Appellants' attack in Ground 1 is closely allied to Grounds 2-5, which also focus on the suggested reliance on the "industry insider" and the Companies' House analysis.

61. The Secretary of State's response is, in essence, that it was rational to conclude that it was not realistically possible to reach reliable conclusions on the impact on pharmacy numbers or distribution, that the PhAS scheme was there to ensure a reasonable distribution of, and access to, community pharmacies, and in that context there was no *Tameside* breach. The Secretary of State rejects the suggestion that there was in fact reliance on the "two sources", at least as determining policy, or other than as background information.

62. We have reviewed the evidence with particular care, with the Appellants' concerns in mind. We conclude that the judge was correct to reject the alleged *Tameside* breach. The decision was not taken in reliance on the "industry insider" and the assumption of a 15% average profit margin, drawn from the Companies House study. It is perhaps unfortunate that the Minister made reference to the assumed 15% profit margins when answering questions in Parliament, at the time of his announcement. However, the successive submissions and documents before the Minister make it clear there was in fact no such assumption. The essential thinking on which the decision proceeded, so far as obtaining information and achieving a proper basis for the decision, was that it was not going to be possible to achieve a reliable estimate of how many pharmacies might close. That central point is expressed a number of times in the documentation, as the extracts set out above demonstrate.

63. In the course of submissions to the judge below and to us, the Appellants have relied on the decision of Treacy J (as he then was) in the High Court of Northern Ireland in *In Re CPNI [2011] NIQB 132*. CPNI is the representative body for pharmacists in Northern Ireland. The case arose from a dispute as to changes in the system of remuneration for pharmacists there, and in that rather basic sense represents a parallel to this litigation. However, the facts were widely different because there was no impact statement, the decision was taken before the end of the consultation period and without taking into account all representations which had been made. Sir James Eadie submits

respectfully that Treacy J's approach to the *Tameside* test was in error. However, it is not necessary for us to consider that matter. In our view, that decision is simply distinguishable on its facts, and cannot materially assist here. That was the conclusion of Collins J, and we consider he was right.

64. The judge expressed his conclusions on the *Tameside* issue as follows:

> "43. The economic impact was obviously of considerable importance. But I have to ask myself whether the failure to obtain a satisfactory analysis of the economic effect did contravene the Tameside principle and whether the failure to disclose such analysis as had been carried out rendered the consultation unfair. It has been submitted that there was a full assessment made in 2011 and that a similar exercise should have been carried out. The defendant's case was that that previous assessment was in his view unsatisfactory and furthermore such an exercise would require time and money which would militate against the overall savings required. PSNC was informed that the Department would welcome any information on the likely effects on pharmacies. I accept Ms Foster's submission that if particular information is indeed needed to produce a proper result it is not, as a general rule, for the decision maker to put the burden on those affected or consultees to provide it. But circumstances may dictate otherwise.
>
> 44. The expertise of PSNC is a relevant factor. Furthermore, as the Department recognised, it was very difficult to obtain any sensible figures of likely closures. While I am surprised that the information was not disclosed, I do not think that such disclosure would have made any difference. PSNC was aware of the percentage involved in the cuts and, since no analysis beyond the 15% suggestion had been made, could have obtained information from in particular the small pharmacies. If it had known what the Department had done, it would have been in no better position. And, as I have said, I do not think that it was irrational of the Department to consider that there was no need to try to obtain any more reliable information, if that were indeed possible, since the cost of so doing outweighed any possible benefit. Furthermore, PSNC could as suggested without too much difficulty have obtained such information as it considered necessary. I appreciate the Department had power to require pharmacies to give relevant information, but again the cost and effort involved in such an exercise was reasonably considered to outweigh its benefit.
>
> 45. It follows that I do not find there to have been any breach of the Tameside principle."

65. We agree. In our view, the Respondent was entitled to conclude that no more certainty or even confidence was achievable as to the number of closures which would result

from the proposals. The variability in business models was such as to preclude that prospect. The Appeal on Ground 1 is dismissed.

66. We have indicated that Grounds 1 and 2 to 5 are closely linked. In our view, the evidence does not bear out the suggestion that the decision relied critically, or even in any important fashion, on the supposed 15% profit margin. The judge expressed his regret that the Respondent Department was not more open about the information shared with the Appellants, and his comments may well be valid. However, the essential points are that the decision did not rest on the "insider" estimate, or the conclusions of the Companies House Survey. The limitations of that information were fully recognised in successive submissions to the Minister, and indeed in the two final critical documents on which the decision was based.

67. In paragraphs 20 and 21 of his judgment, Collins J correctly identified the relevant authority bearing on the requirements of fairness in consultation, where proposed changes will remove existing benefits and may make an existing business and livelihood unviable. We do not consider that he misdirected himself. Rather he was fully alive to the requirements of the law.

68. We reject the contention that the judge fell into error when he declined to condemn the consultation as unlawful. It was regrettable that the process was not more open as to any assumed profit margin, but since no such margin was treated as a critical point in the decision, the point could not render the process unfair.

69. There is no question but that PSNC were aware of the nature of the proposed changes. As the Respondents emphasise, they were closely involved in the process, and made detailed representations, some of which were adopted. From paragraph 25 onward, Collins J summarises the consultation process with the Appellants. From the evidence before us, it would be possible, but is unnecessary, to amplify that account. This was a detailed process, and in our judgment the judge's conclusion that it was lawful cannot be impugned.

70. As the Respondents have observed, the contradiction complained of in Ground 4 "proceeds on the basis that the 15% figure was 'material' to the decision". Since we have concluded that the judge was correct to say it was not so, the submission fails.

71. The same point is fatal in Ground 5. The critique of the supposed 15% profit margin set out in the evidence of Mr Ogier did not require close analysis by the judge, for the same reasons.

Ground 6

72. The complaint here is that the judge failed to grapple with a submission that the Secretary of State could not "lawfully make amendments to the Drug Tariff, which have the effect of radically reforming and reshaping the community pharmacy market". Very limited written or oral submissions were made to us on this point. In essence, the suggestion is that there was a settled intention to reduce the number of pharmacies, and that it was unlawful to achieve that end through pricing alterations.

73. The Respondents fairly comment that this argument was not raised in the Grounds for judicial review, but was introduced for the first time in the Appellants' skeleton argument below.

74. The Judge's conclusion was that the evidence did not bear out a positive intention to reduce the number of community pharmacies; rather the changes were made as a means of delivering the cost savings planned. And whilst a reduction in the number of pharmacies was expected, as we have by now emphasised more than once, the evidence demonstrates that the Respondents were unsure how many would eventuate. He therefore concluded:

> "29. While I have no doubt that a reduction in the number of pharmacies was regarded by the Department and ministers as desirable, the changes were not made with that intention. The changes were to save cost and to implement the required savings that were dictated by the government. It was submitted (albeit this was not a ground in respect of which permission had been granted) that the changes were made for the improper purpose of reducing the number of pharmacies. That such reductions were regarded as a desirable effect of the changes to remuneration seems to me to be clear, but that does not mean that that was the intention behind those changes. It is submitted that a decision maker must be deemed to intend the inevitable consequences of his action. But that does not mean that the action is for an improper purpose even if the changes have the effect of closing some pharmacies."

75. We see no error in that conclusion. Even if a reduction in the numbers was expected, and was thought desirable in general terms, there is no principle of law which could mean that alteration in a publicly funded pricing mechanism such as the Drug Tariff, otherwise justified as a means of achieving legitimate savings, is rendered unlawful by such anticipated consequences. This ground, too, fails.

The Equality Ground of Appeal

76. Mr Lock QC for the NPA relies upon a single additional ground of appeal. He submits that section 1C of the 2006 Act assumes that (i) there are significant health inequalities in England, and (ii) making NHS services equally available to anyone who chooses to access them does not, of itself, reduce existing health inequalities, because different groups of patients do not take the same advantage of that opportunity of access. In exercising his functions under the 2006 Act, section 1C requires the Secretary of State to consider how he can exercise those functions to reduce the inequalities in benefits people in England can obtain from NHS services. Mr Lock submits that, in this case, the Secretary of State failed to do so. In particular, as evidenced in the Duties Document, the Secretary of State focused exclusively on securing maintenance of access to a community pharmacy for the purpose of obtaining prescription drugs, and thus erred in misunderstanding the nature of the section 1C duty which is concerned with:

i) not merely access to NHS services, but the inequalities of benefits obtained from such services;

ii) not merely ensuring that inequalities do not become worse, but that they are reduced; and

iii) not merely the fulfilment of NHS prescriptions, but meeting the other obligations of an NHS pharmacist under the 2013 Regulations, such as providing advice and support (see [6] above).

77. This misunderstanding, Mr Lock submits, is revealed in the Duties Document in a number of ways. For example:

i) He submitted that the decision was based on the assumption that NHS expenditure could be reduced without affecting the quality of services received by patients because, although the cuts in funding were likely to lead to closure of pharmacies, it was most likely that those pharmacies would be part of a cluster and so they could close because patients would be able to access adequate services from other community pharmacies in the cluster within easy reach. However, that conclusion was based only on access to the facility to dispense drugs, and ignored the effect of closures on other services provided by community pharmacies in areas of multiple deprivation. Given the paucity of GPs in those areas, those services are vital. When other services were taken into account, the evidence was that those pharmacies are currently working without any spare capacity. The assumption upon which the decision proceeded therefore had no sound foundation.

ii) Furthermore, Mr Lock argues it is clear from the Duties Document that the PhAS would not offer any protection for pharmacies in clusters, but rather would benefit isolated areas by ensuring continued access to a pharmacy [172]; and that, consequently, "there may be a disproportionate effect on deprived communities, were any closures to occur". Mr Lock complains that the practical effect of the decision was thus to exacerbate existing inequalities in benefits that patients get from NHS services, by moving funding away from communities that had the highest level of health inequities and adding subsidy to relatively affluent areas of the country where there are no or lower levels of health inequities.

iii) The Duties Document accepted that delivering services in minority languages was a benefit to NHS patients, but purposely did not take that factor into account when designing the PhAS (see [67-68] of the Duties Document). Mr Lock submitted that this failure is a further example of how the effects of the decision on the non-prescription services provided by pharmacists were (it is submitted, wrongly) ignored.

Discussion

78. We are unpersuaded that, in making the decision as he did, the Secretary of State breached section 1C of the 2006 Act, for the following reasons.

79. As with many decisions by a public body, the Secretary of State made the challenged decision on the basis of a number of documents provided by his officials, including (importantly for the purposes of this appeal) the Impact Assessment and Duties Document. These documents are designed primarily to assist the Secretary of State to

make a decision. They are not to be subjected to the same exegesis that might be appropriate for the interpretation of a statute. What is required is a fair and straightforward reading of the documents as a whole, in their full context, which includes the fact that they are addressed to the Secretary of State and thus to a knowledgeable reader. In the absence of evidence to the contrary, it can be assumed that the Secretary of State considered both these documents, and adopted their analysis, reasoning and conclusions, rather than focussing only on the Duties Document.

80. The duty in section 1C is to have "regard to the need to reduce inequalities between people in England with respect to the benefits they can obtain from the health service". We accept that, as Mr Lock submits, this provision assumes that there are inequalities between people, not simply as a result of different opportunities to access NHS services, but in benefits that are in practice obtained from available services. The provision requires the Secretary of State, when exercising any function under the 2006 Act, to have regard to the need to reduce such inequalities.

81. However, in exercising his functions in relation to the health services, the Secretary of State has a substantial degree of flexibility as to how he goes about his task. As we have described, the 2006 Act imposes a number of different "high level" duties upon him to have regard to a wide and disparate range of factors and aims in exercising those functions, which are both complex and potentially conflicting, particularly as the discharge of the functions will inevitably involve the allocation of limited resources between competing needs. For example, whilst his overarching duty in section 1 is to "continue the promotion in England of a comprehensive health service", he must also exercise his functions both "with a view to securing continuous improvement in the quality of services provided to individuals..." (section 1A) and "having regard to the need to reduce inequalities between people of England with respect to the benefits they can obtain from the health service" (section 1C). There might be tension between those aims and objects in a particular case. But these are only examples of the factors that the Secretary of State is required to take into account in the exercise of his statutory functions. There are patently many other material factors which he is entitled to take into consideration. It is self-evident that these various considerations are complex, socio-economic in nature and potentially in conflict. In balancing these factors, the functions allocated to the Secretary of State under the 2006 Act clearly involve the exercise of substantial discretion, judgment or assessment.

82. In performing that exercise, as Sir James submitted, it is well-established that any consideration by the court of compliance with a duty to "have regard" to a particular factor involves a review of the process and not the merits. In *R (Khatun) v London Borough of Newham* [2004] EWCA Civ 55; [2005] QB 37, having referred to *CREEDNZ Inc v Governor General of New Zealand* [1981] 1 NZLR 172 and *In re Findlay* [1985] AC 318, Laws LJ at [35] said this:

> "In my judgment *CREEDNZ* (via the decision in *Findlay*) does not only support the proposition that where a statute conferring discretionary power provides no lexicon of the matters to be treated as relevant by the decision-maker, then it is for the decision-maker and not the court to conclude what is relevant, subject only to *Wednesbury* review. By extension it gives authority also for a different but closely related proposition, namely that it is for the decision-maker and not the court, subject

> again to *Wednesbury* review, to decide upon the manner and intensity of enquiry to be undertaken into any relevant factor accepted or demonstrated as such."

83. In *R (Hurley and Moore) v Secretary of State for Business Innovation and Skills* [2012] EWHC 201 (Admin), which concerned the PSED to have due regard to the need to eliminate discrimination, Elias LJ (with whom King J agreed) said:

> "77. ... I do not accept that this means that it is for the court to determine whether appropriate weight has been given to the duty. Provided the court is satisfied that there has been a rigorous consideration of the duty, so that there is a proper appreciation of the potential impact of the decision on equality objectives and the desirability of promoting them, then as Dyson LJ in *R (Baker & Ors) v Secretary of State for the London Borough of Bromley* [2008] EWCA 141 at [34] made clear, it is for the decision maker to decide how much weight should be given to the various factors informing the decision.
>
> 78. The concept of 'due regard' requires the court to ensure that there has been a proper and conscientious focus on the statutory criteria, but if that is done, the court cannot interfere with the decision simply because it would have given greater weight to the equality implications of the decision than did the decision maker. In short, the decision maker must be clear precisely what the equality implications are when he puts them in the balance, and he must recognise the desirability of achieving them, but ultimately it is for him to decide what weight they should be given in the light of all relevant factors. If Ms Mountfield's submissions on this point were correct, it would allow unelected judges to review on substantive merits grounds almost all aspects of public decision making.

84. The weight, if any, to be given to relevant factors in such circumstances is thus essentially a matter for the public body assigned by Parliament to make the relevant decision; and the courts have emphasised the importance of not imposing too high a burden on such decision-makers.

85. For example, in relation to the PSED, in *R (Bailey) v Brent London Borough Council* [2011] EWCA Civ 1586 at [201], Davis LJ said this:

> "Councils cannot be expected to speculate on or to investigate or to explore such matters ad infinitum; nor can they be expected to apply, indeed they are to be discouraged from applying, the degree of forensic analysis for the purposes of... consideration of their duties under section 149 which a QC might deploy in court."

In *R (Greenwich Community Law Centre) v Greenwich London Borough Council* [2012] EWCA Civ 496 at [30], Elias LJ succinctly put it thus:

> "The courts must ensure that they do not micro-manage the exercise."

More recently, in *R (West Berkshire District Council) v Secretary of state for Communities and Local Government* [2016] EWCA Civ 441; [2016] 1 WLR 3923 at [83], Laws and Treacy LJJ made clear that the requirement to pay due regard to equality impact in section 149 of the Equality Act 2010 "is just that. It does not require a precise mathematical exercise to be carried out in relation to the particular affected groups....". An equality statement, they said, could and should take "a relatively broad-brush approach"; and that, in the case before them, the judge erred in adopting "a more stringent and searching approach" (see [85]).

86. Whilst these cases concerned a statutory requirement "to have *due* regard", rather than simply "to have regard", like the judge below, we do not consider it is necessary for the purposes of this appeal to determine what, if any, difference the addition of the word "due" makes. There is authority to the effect that "due" emphasises the quality (or, perhaps, intensity) of the consideration which the decision-maker must give to the relevant factor (*R (MS) v Oldham Metropolitan Borough Council* [2010] EWHC 802 (Admin) at [18] per Langstaff J); or that it may give the court some greater power to investigate the question of whether the regard that has been given was proper and appropriate in the circumstances (*R (Meany) v Harlow District Council* [2009] EWHC 559 (Admin) per Davis J, as he then was). But in this case, the statutory duty is simply "to have regard" to the relevant inequalities, and any greater burden imposed upon a decision-maker by the word "due" is clearly not imposed here.

87. In our view, it cannot be said that the Secretary of State paid *no* regard to the section 1C duty. As we have indicated, it can be assumed that he considered everything within the Duties Document. In the part of that document which went through each of the high-level duties imposed by the 2006 Act, there is a two-page section that deals with the section 1C duty, quoted at [48] above. Mr Lock accepted that, in [163] and [164], the Duties Document properly identified and accurately set out the duty: as we have described, [163] did correctly paraphrase the duty, and the following paragraph, having identified the relevant inequalities, emphasised that the duty is "about a need to reduce" the inequalities which it had described. It emphasised that those inequalities may or may not be based on protected characteristics. So:

> "Socio-economic impacts need therefore to be considered in terms of other socio-economic factors such as income, social deprivation and rural isolation."

88. But, having correctly identified the nature and scope of the duty, Mr Lock submitted that the Duties Document then ignored them: it lost the required focus and considered only the pharmacy footprint, i.e. access to pharmacies rather than the extent to which in practice groups avail themselves of the benefits provided by pharmacies. We do not consider that a fair reading of that section of the document supports that contention.

89. In his submissions, Mr Lock focused on one group of pharmacy customers, namely those in areas of multiple deprivation. However, [166] of the Duties Document identified not one but two particular concerns, namely that the effect of the decision on the profitability of pharmacy contractors might have a disproportionately detrimental impact on pharmacy customers in two areas.

i) "Areas where there might inevitably be less choice because of demographic factors". These were essentially rural areas, where pharmacy provision might be sparse compared with other areas. The PhAS was expected to mitigate the impact of any potential pharmacy closures that might result in people in isolated areas having less than reasonable access to a pharmacy at all [168].

ii) "Less affluent areas". These are the areas of particular concern to the NPA. This issue was dealt with in the Duties Document under the heading "Impact on deprived areas" in [169-174]. There was reference to research which suggested that deprived areas tend to have more clustering; and [171] specifically considered whether deprived areas could be adversely affected by the policy. However, it noted that clusters of pharmacies do not necessarily reflect need; and that pharmacies may consequently operate to benefit from "the higher footfall" and would continue to be viable without PhAS.

90. The cuts in funding for pharmacies were unprecedented, and it is clear from the Impact Statement and Duties Document that, of these two factors, the need to maintain what was considered reasonable access to pharmacies, notably in rural areas, was given considerable weight. The Secretary of State was clearly entitled to give that factor that weight, particularly in the light of his section 1 duty in relation to maintaining a comprehensive health service. In any event, as Sir James Eadie submitted, social deprivation is an important socio-economic factor that affects health inequalities; but it is not the only one. It is obvious that living in an area where there are no pharmacies at all, as opposed to an area where there are multiple pharmacies within a one-mile radius, can also affect the ability of patients to obtain benefits from the health service, leaving aside the benefits of choice that an area of multiple pharmacies provides and of which more rural areas are already deprived. In exercising his NHS functions, as well as having regard to the need to reduce existing inequalities with respect to the benefits patients can obtain from the NHS, the Secretary of State of course must (or, at least, is entitled to) take into account potential new inequalities and disadvantages to groups of NHS patients that might arise from the exercise of his functions. Thus, in our view, Mr Lock's submission – that the support of pharmacies in rural areas by way of the PhAS exacerbated present health and health outcome inequalities by subsidising those areas at the cost of areas of multiple deprivation in which such inequalities are high – overmuch concentrates on one particular aspect of the multifactorial broad-brush assessment required on the Secretary of State by the statutory scheme. In our view, that is a fatal flaw in Mr Lock's submissions.

91. Although not directly relevant to the issue with which this appeal is concerned, it comes as some comfort that the evidence shows that the proportion of funding for community pharmacies that goes to deprived areas has not in fact fallen as a result of implementation of the decision including the PhAS. As we have described (see [15] above), areas of greater deprivation have been historically disproportionately well-funded from the community pharmacy budget. The evidence of Ms Howe, which is uncontroverted, is that the implementation of the decision (at least as at 1 February 2016) had not had a significant effect on the distribution of the funding for community pharmacies in the sense that the percentage funding for each decile based on the Index of Multiple Deprivation has remained unchanged ([83] of her statement of 1 February 2016).

92. Nor do we consider that the Secretary of State's focus upon ensuring that current inequalities do not become worse as a result of the decision, betrays any misapplication of section 1C. He was entitled to consider that, in implementing the unprecedented reduction in the funding of community pharmacies, the maintenance of reasonable universal access to pharmacy services should be given greater weight than the need to reduce the inequalities with which section 1C is concerned. In having regard to the need to reduce those inequalities over time, the Secretary of State was entitled to proceed on the basis that the correct balance between competing policies would be met by maintaining reasonable access in all areas whilst not having any significant detrimental effect on the pharmacy services provided in less affluent areas, where these inequalities are currently higher. Simply because the Secretary of State gave those different policies the weight that he did, is not in itself evidence that he failed properly to have regard to the need to reduce the inequalities upon which section 1C focuses.

93. In our view, given the history of the rapid growth of pharmacies in urban areas, in which the large majority of new pharmacies there entered the market without having to establish any health need, the Secretary of State was also entitled to proceed on the basis that the clustering of pharmacies in urban areas of multiple deprivation did not – or, as the Duties Document put it (in [171]), did not necessarily – reflect health need.

94. Similarly, just because, in making his assessment, the Secretary of State focused on fulfilment of NHS prescriptions, that does not mean that he failed to take into account the other services community pharmacies provide. He was entitled to give particular weight to the primary function of community pharmacies, which is to dispense NHS prescriptions. But in any event, as Sir James Eadie submitted, the documents upon which the decision was based expressly referred to such other services. For example, the Impact Assessment:

    i) specifically referred to the fact that: "All pharmacies are required to provide essential services, which include dispensing, prescription-linked healthy lifestyle advice, and support for self-care within a clinical governance framework" [2(i)];

    ii) in the discussion of "impacts on the quality or services offered by pharmacists" and "impacts on other parts of the NHS" in [84-88], specifically referred to the fact that "community pharmacies may also be used by patients as a source of health information and advice" [86]; and

    iii) addressed in detail a report commissioned by the PSNC about the value of services provided by community pharmacies other than dispensing (Annex B).

    There is no evidential basis for the proposition that the Secretary of State did not consider this aspect of the services provided by community pharmacies. Looking at the documents as a whole, fairly read, in our view it cannot be said that the Secretary of State did not take into account the value of pharmacies providing services over and above meeting prescriptions. The weight he gave to that factor was, of course, a matter for the Secretary of State.

95. Mr Lock submitted that the Secretary of State was wrong to assume that, in an area of multiple pharmacies, the closure of one or more would not reduce the level of service

to NHS patients, over and above the restriction in choice that would result. However, we accept Sir James Eadie's submission that there was no error in law here either.

i) Mr Lock relied upon anecdotal evidence that, prior to the decision, community pharmacies in areas of multiple deprivation, despite being geographically close to one another, often in clusters, were working at capacity in the sense that, on the basis of current working arrangements, they could not achieve a significant rise in the level of services (and notably services other than meeting prescriptions). However, although subject to some degree of regulation, pharmacies are commercial enterprises. The decision generally made funding more directly proportionate to the amount of services provided. In our view it was clearly reasonable for the Secretary of State to assume that, following the implementation of the decision and any closures of cluster pharmacies, market forces would operate and the remaining pharmacies would meet any otherwise unsatisfied demand as a result of the closures, the costs relating to an increase in activity being met by an increase in income by (e.g.) expanding their business and/or changing their working arrangements. We do not consider that the very limited amount of anecdotal evidence as to what has happened to particular pharmacies as a result of the implementation of the decision in any way undermines the reasonableness of that assumption.

ii) Mr Lock submits that, prior to making the assumptions that he did, the Secretary of State should have conducted an assessment of whether "NHS pharmacies operating in areas of multiple deprivation have the capacity to expand the services they provide to NHS patients so as to be able to provide an appropriate level of advice and support for NHS patients as a result of any NHS community pharmacy that closes as a result of the decision". Mr Lock did not expand on what such an assessment would involve. Sir James Eadie submitted that it would require the Secretary of State to consider and draw conclusions on a number of matters relating to individual pharmacies, including the pharmacy's current demand, income, resources and other commercial circumstances; its likely future financial performance, prognosis and viability after the implementation of the decision; how many and which of the pharmacies would likely close; and the effects of pharmacy closures for other particular pharmacies. He submitted, with some force, that such an exercise would be impracticable, given the work involved and the inherently dynamic nature of the market. Certainly, we are unpersuaded that the Secretary of State's duty to have regard to the need to reduce health inequalities required such an exercise. Indeed, it seems to us that it would go well beyond the broad-brush assessment that the duty requires.

96. Mr Lock also submitted that the authors of the Duties Document erred in accepting that delivering services in minority languages was a benefit to NHS patients, but then failing to take that factor into account when designing the PhAS. However, that was because, where a need for translation services as a part of the NHS is identified, such services are "enhanced services", and are locally commissioned by reference to local need. They are commissioned separately and come from a different budget. Thus, the Secretary of State did not arguably err in not taking them into account in relation to the implementation of his policy by way of the decision.

97. Finally, Mr Lock made a particular submission in the course of argument that, if there was no difference between having "regard" and having "due regard", the Secretary of State erred in not applying the approach commended by this court in *Bracking v Secretary of State for Work and Pensions* [2013] EWCA Civ 1345. That case concerned the application of the PSED in the context of the closing of a benefits fund, the Independent Living Fund. In that context, at [26], McCombe LJ (with whom, on this point, neither Kitchin LJ nor Elias LJ disagreed), set out eight propositions that he derived from the large numbers of authorities to which the court had been referred. Mr Lock did not identify any propositions upon which he particularly relied, as having not being met by the Secretary of State in this case. McCombe LJ emphasised that the statutory criteria must be both consciously and rigorously considered (see [26(6) and (8)]); but, in our view, there is no evidence that the Secretary of State here was wanting on that score. He stressed that the decision-maker must "assess the risk and extent of any adverse impact and the ways in which such risk may be eliminated..."; but here the Secretary of State clearly had very much in mind the potential adverse impact on those in deprived areas, and concluded that they would not be substantially worse. In the context of the exercise as a whole and of his other obligations, that was acceptable in the light of the section 1C obligation. McCombe LJ also emphasised that, so long as the decision-maker had a proper appreciation of the potential impact of the decision on the statutory objectives and the desirability of promoting them, then it is for him to decide how much weight should be given to the various factors that informed his decision (see [26(8)(i)]). In our view, *Bracking* does not assist Mr Lock in this case.

98. We do not find that the NPA ground has been made good.

Conclusion

99. For those reasons, both appeals are dismissed.

ANNEX 1

NATIONAL HEALTH SERVICE ACT 2006

Part 7 Pharmaceutical services and local pharmaceutical services

126 Arrangements for pharmaceutical services

(1) Each Primary Care Trust must, in accordance with regulations, make the arrangements mentioned in subsection (3).

(2) The Secretary of State must make regulations for the purpose of subsection (1).

(3) The arrangements are arrangements as respects the area of the Primary Care Trust for the provision to persons who are in that area of—

(a) proper and sufficient drugs and medicines and listed appliances which are ordered for those persons by a medical practitioner in pursuance of his functions in the health service, the Scottish health service, the Northern Ireland health service or the armed forces of the Crown,

(b) proper and sufficient drugs and medicines and listed appliances which are ordered for those persons by a dental practitioner in pursuance of—

(i) his functions in the health service, the Scottish health service or the Northern Ireland health service (other than functions exercised in pursuance of the provision of services mentioned in paragraph (c)), or

(ii) his functions in the armed forces of the Crown,

(c) listed drugs and medicines and listed appliances which are ordered for those persons by a dental practitioner in pursuance of the provision of primary dental services or equivalent services in the Scottish health service or the Northern Ireland health service,

(d) such drugs and medicines and such listed appliances as may be determined by the Secretary of State for the purposes of this paragraph and which are ordered for those persons by a prescribed description of person in accordance with such conditions, if any, as may be prescribed, in pursuance of functions in the health service, the Scottish health service, the Northern Ireland health service or the armed forces of the Crown, and

(e) such other services as may be prescribed.

(4) The descriptions of persons which may be prescribed for the purposes of subsection (3)(d) are the following, or any sub-category of such a description—

(a) persons who are registered in the register maintained under article 5 of the Health Professions Order 2001,

(b) persons who are registered pharmacists,

...

(5) A determination under subsection (3)(d) may—

(a) make different provision for different cases,

(b) provide for the circumstances or cases in which a drug, medicine or appliance may be ordered,

(c) provide that persons falling within a description specified in the determination may exercise discretion in accordance with any provision made by the determination in ordering drugs, medicines and listed appliances.

(6) The arrangements which may be made by a Primary Care Trust under subsection (1) include arrangements for the provision of a service by means such that the person receiving it does so otherwise than at the premises from which it is provided.

(7) Where a person with whom a Primary Care Trust makes arrangements under subsection (1) wishes to provide services to persons outside the area of the Primary Care Trust he may, subject to any provision made by regulations in respect of arrangements under this section, provide such services under the arrangements.

(8) The services provided under this section are, together with additional pharmaceutical services provided in accordance with a direction under section 127, referred to in this Act as "pharmaceutical services".

(9) In this section—

"armed forces of the Crown" does not include forces of a Commonwealth country or forces raised in a colony,

"listed" means included in a list approved by the Secretary of State for the purposes of this section,

"the Scottish health service" means the health service within the meaning of the National Health Service (Scotland) Act 1978 (c. 29), and

"the Northern Ireland health service" means the health service within the meaning of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I.14)).

127 Arrangements for additional pharmaceutical services

(1) The Secretary of State may—

(a) give directions to a Primary Care Trust requiring it to arrange for the provision to persons within or outside its area of additional pharmaceutical services, or

(b) by giving directions to a Primary Care Trust authorise it to arrange for such provision if it wishes to do so.

(2) Directions under this section may require or authorise a Primary Care Trust to arrange for the provision of a service by means such that the person receiving it does so otherwise than at the premises from which it is provided (whether those premises are inside or outside the area of the Primary Care Trust).

(3) The Secretary of State must publish any directions under this section in the Drug Tariff or in such other manner as he considers appropriate.

(4) In this section—

"additional pharmaceutical services", in relation to directions, means the services (of a kind that do not fall within section 126) which are specified in the directions, and

"Drug Tariff" means the Drug Tariff published under regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I. 1992/662) or under any corresponding provision replacing, or otherwise derived from, that regulation.

128 Terms and conditions, etc

(1) Directions under section 127 may require the Primary Care Trust to which they apply, when making arrangements—

(a) to include, in the terms on which the arrangements are made, such terms as may be specified in the directions,

(b) to impose, on any person providing a service in accordance with the arrangements, such conditions as may be so specified.

(2) The arrangements must secure that any service to which they apply is provided only by a person—

(a) whose name is included in a pharmaceutical list, or

(b) who has entered into a pharmaceutical care services contract under section 17Q of the National Health Service (Scotland) Act 1978.

128A Pharmaceutical needs assessments

(1) Each Primary Care Trust must in accordance with regulations—

(a) assess needs for pharmaceutical services in its area, and

(b) publish a statement of its first assessment and of any revised assessment.

(2) The regulations must make provision—

(a) as to information which must be contained in a statement;

(b) as to the extent to which an assessment must take account of likely future needs;

(c) specifying the date by which a Primary Care Trust must publish the statement of its first assessment;

(d) as to the circumstances in which a Primary Care Trust must make a new assessment.

(3) The regulations may in particular make provision—

(a) as to the pharmaceutical services to which an assessment must relate;

(b) requiring a Primary Care Trust to consult specified persons about specified matters when making an assessment;

(c) as to the manner in which an assessment is to be made;

(d) as to matters to which a Primary Care Trust must have regard when making an assessment.

129 Regulations as to pharmaceutical services

(1) Regulations must provide for securing that arrangements made by ... the Board under section 126 will—

(a) enable persons for whom drugs, medicines or appliances mentioned in that section are ordered as there mentioned to receive them from persons with whom such arrangements have been made, and

(b) ensure the provision of services prescribed under subsection (3)(e) of that section by persons with whom such arrangements have been made.

(2) The regulations must include provision—

(a) for the preparation and publication by ... the Board of one or more lists of persons, other than medical practitioners and dental practitioners, who undertake to provide pharmaceutical services ...

(b) that an application to ... the Board for inclusion in a pharmaceutical list must be made in the prescribed manner and must state—

(i) the services which the applicant will undertake to provide and, if they consist of or include the supply of appliances, which appliances he will undertake to supply, and

(ii) the premises from which he will undertake to provide those services,

...

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

Regulation 89

(1) The Drug Tariff referred to in section 127(4) of the 2006 Act (arrangements for additional pharmaceutical services) is the aggregate of—

(a) the determinations of remuneration made by the Secretary of State, acting as a determining authority, under section 164 of the 2006 Act(1) (remuneration for persons providing pharmaceutical services), but not of the remuneration of dispensing doctors;

(b) the determinations of remuneration made by the NHSCB, acting as a determining authority, pursuant to regulation 91(1); and

(c) any other instruments that the Secretary of State is required by virtue of these Regulations or the 2006 Act to publish, or does publish, together with those determinations,

in the publication known as the Drug Tariff, which the Secretary of State shall publish in such format as the Secretary of State thinks fit.

(2) Determinations under section 164 of the 2006 Act by the Secretary of State or the NHSCB may be made by reference to—

(a) the drugs and appliances dispensed or expected to be dispensed in accordance with NHS prescriptions during a reference period determined by the Secretary of State;

(b) lists of published prices produced by suppliers of the drugs or appliances that are available from them on NHS prescription;

(c) scales, indices or other data that relate to volume and price that are produced by suppliers of the drugs or appliances that are available from them on NHS prescription; and

(d) any other scales, indices or other data (including formulae) by reference to which the Secretary of State considers it appropriate to make such a determination, and in these circumstances, the Secretary of State may provide that remuneration is to be determined by reference to data which is—

(i) in the form current at the time of the determination; and

(ii) in any subsequent form taking effect after that time.

(3) Amendments may be made to the Drug Tariff at such intervals as the Secretary of State thinks fit, but must be published in a consolidated version of the Drug Tariff that has the amendments included in it.

(4) The consultation that the Secretary of State must undertake under section 165(1) of the 2006 Act (section 164: supplementary) prior to the inclusion of, or change to, a price of a drug or appliance which is to form part of a calculation of remuneration shall be by way of consultation on the process for determining the price to be included or changed, not on the proposed price itself (unless it is impossible to carry out an effective consultation in any other way).

...

Regulation 90

(1) The data which the Secretary of State and the NHSCB may take into account prior to making a determination under section 164 of the 2006 Act(1) (remuneration for persons providing pharmaceutical services) may include information obtained pursuant to paragraph (3) by—

(a) the Secretary of State or a person appointed by the Secretary of State under this paragraph; or

(b) the NHSCB or a person appointed by the NHSCB under this paragraph,

and a person appointed under this paragraph is referred to in this regulation as "a nominee".

(2) Before appointing a person to be a nominee, the Secretary of State or the NHSCB must consult, as they consider appropriate, organisations representative of the NHS chemists to whose remuneration the possible determination arising out of the data would relate.

(3) An NHS chemist must, within 30 days of a request to do so, provide—

(a) the Secretary of State or a nominee of the Secretary of State with information (for example invoices) which the Secretary of State considers to be relevant to the matters the Secretary of State may take into account prior to making a determination under section 164 of the 2006 Act; or

(b) the NHSCB or a nominee of the NHSCB with information (for example invoices) which the NHSCB considers to be relevant to the matters the NHSCB may take into account prior to making a determination under section 164 of the 2006 Act.

(4) A nominee may handle and process information obtained under paragraph (3).

(5) The Secretary of State may require—

(a) information obtained by a nominee of the Secretary of State under paragraph (3)(a) to be obtained; and

(b) information processed or handled by a nominee of the Secretary of State under paragraph (4) to be processed or handled,

in such manner as the Secretary of State may reasonably specify.

(6) The NHSCB may require—

(a) information obtained by a nominee of the NHSCB under paragraph (3)(b) to be obtained; and

(b) information processed or handled by a nominee of the NHSCB under paragraph (4) to be processed or handled,

in such manner as the NHSCB may reasonably specify.

(7) The Secretary of State and the NHSCB may share with each other information which they or their nominees have obtained under this regulation (for purposes related to the determination of pharmaceutical remuneration).

ANNEX 2

Table 8 – Operating profit margin of pharmacies by pharmacy size and company type

		Small Less than 4,030 items per month	**Medium** 4,030 to 8,750 items per month	**Large** More than 8,750 items per month
Independent Single Pharmacy	Min	1.8%	1.1%	-2.3%
	Max	18.3%	20.0%	11.4%
	Mean	7.4%	7.2%	3.5%
	# in sample	7	9	10
Chain 2-20 Pharmacies	Min	4.8%	5.6%	-5.6%
	Max	4.8%	5.6%	28.0%
	Mean	4.8%	5.6%	5.9%
	# in sample	1	1	33
Multiple 21+ Pharmacies	Min	5.6%	4.3%	-9.9%
	Max	32.3%	4.3%	29.1%
	Mean	19.4%	4.3%	5.6%
	# in sample	2	1	15

Table 9 – Operating profit per shop (for the company) by pharmacy size and company type

		Small Less than 4,030 items per month	**Medium** 4,030 to 8,750 items per month	**Large** More than 8,750 items per month
Independent Single Pharmacy	Min	£6,236	£21,221	£-370,241
	Max	£1,038,778	£222,732	£888,188
	Mean	£268,413	£100,038	£160,442
	# in sample	7	9	10
Chain 2-20 Pharmacies	Min	£130,250	£12,557	£-219,930
	Max	£130,250	£12,557	£298,762
	Mean	£130,250	£12,557	£72,900
	# in sample	1	1	33
Multiple 21+ Pharmacies	Min	£17,715	£10,621	£-90,422
	Max	£452,664	£10,621	£361,768
	Mean	£235,189	£10,621	£66,319
	# in sample	2	1	15