

Annexe E

Regulation of the medicines sector

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ANNEXE E

REGULATION OF THE MEDICINES SECTOR

Introduction

1.1. This Annexe presents information relating to the regulation of the prescription medicines sector. The subjects covered in this Annexe are the following:

- **Section A:** Regulation of manufacture and distribution.
- **Section B:** Regulation of advertising, prescribing and dispensing.
- **Section C: Pricing and reimbursement**
 - C.1 The PPRS
 - C.2 Drug tariffs and reimbursement.
- **Section D:** Application by wholesalers for interim injunction against the implementation of Pfizer's DTP Scheme.

SECTION A – REGULATION OF MANUFACTURE AND DISTRIBUTION

Council Directive 2001/83/EC

- 1.2. Council Directive 2001/83/EC¹ consolidated a number of existing directives relating to medicinal products and is based, primarily, on Article 95 EC Treaty, the single market legal base. The Directive as amended is implemented in the UK by a number of legislative instruments. The most relevant to this study are the Medicines Act 1968 (amended to implement the Directive) and The Medicines for Human use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (the 2005 Regulations).²

The Medicines Act 1968

- 1.3. The Medicines Act provides³ that those who, among other things sell, supply, export, wholesale deal or manufacture any medicinal product are required to hold the necessary licence. Conducting any of the specified activities without the necessary licence constitutes an offence.⁴
- 1.4. Section 28 of the Act provides a general power to the licensing authority, the Medicines and Healthcare Regulatory Authority, to suspend, revoke or vary a licence and lists the grounds on which that power may be exercised.

The Medicines for Human use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

- 1.5. The Regulations establish, among other things, standard provisions for the licences required by sections 7 and 8 of The Medicines Act.⁵ In particular, regulations 2 to 7 relate to the licenses of those who manufacture and assemble relevant medicinal products and regulations 8 to 11 to wholesale dealers. Those regulations require, among other things, that the holder of a wholesale dealer's licence (required for the sale or distribution of relevant medicinal products)⁶ shall:

'...ensure, within the limits of his responsibility as a distributor of relevant medicinal products, the appropriate and continued supply of such relevant medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstance corresponding to retail sale so that the needs of patients in the United Kingdom are covered'.⁷

¹ As amended by Directives 2002/98/EC, 2004/24 EC and 2004/27/EC.

² SI 2005/2789.

³ Sections 7 and 8.

⁴ Section 45.

⁵ In exercise of the power contained in s.47(1) of the Medicines Act 1968.

⁶ Sections 8(3) and 8(3A) Medicines Act 1968.

⁷ Regulation 8(1)(b).

- 1.6. This mirrors the obligation in Article 81 of Directive 2001/83. Manufacturers who distribute by way of wholesale dealing are by virtue of regulation 2(3)(j) of those 2005 Regulations required to comply among things, with the same obligation.
- 1.7. The regulations also require that licence holders comply with the principles and guidelines of good manufacturing practice⁸ and the guidelines on good distribution practice,⁹ as appropriate. Failure to comply with those guidelines to a material extent gives the MHRA the power, under section 28 of the Medicines Act, to vary, revoke or suspend the licence of the party in breach.
- 1.8. The holder of a wholesale dealer's licence is required, among other things, to have in place procedures to conduct an effective recall of medicines where ordered by the MHRA or the competent authority of another EEA State.¹⁰

Guidelines on Good Distribution Practice of Medicinal Products for Human Use¹¹

- 1.9. The four page Guidelines are published by the European Commission pursuant to Article 84 of Directive 2001/83, following consultation with the Committee for Medicinal Products for Human Use and the Pharmaceutical Committee established by Council Decision 75/320/EEC. Their introduction states explicitly that they do not cover the commercial relationships between parties involved in the distribution of medicinal products.
- 1.10. The Guidelines are aimed at maintaining, through the distribution chain, a high level of quality assurance which, by other legislative instruments, the EC seeks to ensure at the manufacturing stage:

'...so that authorised medicinal products are distributed to retail pharmacists and other persons entitled to sell medicinal products to the general public without any alteration of their properties. The concept of quality management in the pharmaceutical industry is described in Chapter I of the Community Guide to Good Manufacturing Practice for medicinal products and should be considered when relevant for the distribution of medicinal products.

The quality system operated by distributors (wholesalers) of medicinal products should ensure that medicinal products that they distribute are authorised in accordance with Community legislation, that storage conditions are observed at all times, including during transportation, that

⁸ Regulation 2(1)(a).

⁹ Regulation 8(1)(a).

¹⁰ Regulation 8(4)(b).

¹¹ This can be found at

<http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2001/may/gdpguidelines1.pdf>.

contamination from or of other products is avoided, that an adequate turnover of the stored medicinal products takes place and that products are stored in appropriately safe and secure areas. In addition to this, the quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period. A tracing system should enable any faulty product to be found and there should be an effective recall procedure'.

- 1.11. The Guidelines go on to deal individually with a number of topics, including personnel, documentation (including as to orders and as to written procedures for a number of different activities), premises and equipment, deliveries and returns. In the context of this market study and the issue of the availability of medicines, the most relevant provision is paragraph 19:

'In case of emergency, wholesalers should be in a position to supply immediately the medicinal products that they regularly supply to the persons entitled to supply the products to the public'.

For the sake of clarity, 'wholesale distribution of medicinal products was defined in Directive 92/25, under which these guidelines were prepared, as 'all activities consisting of procuring, holding, supplying or exporting medicinal products', such that logistics service providers operating under a direct to pharmacy scheme would fall within their scope.

Qualified and Responsible Persons

Qualified Person

- 1.12. Article 48 of Directive 2001/83¹² requires that the holder of a manufacturer's licence have permanently and continuously at their disposal a Qualified Person (QP), the eligibility criteria for which are set out in Article 49 (they should have a university degree covering at least two specified sciences and at least two years' practical experience in business relevant to the manufacture of medicines). That person must be identified to the competent authority (in the UK the MHRA). The QP will be routinely assessed by the MHRA against the Code of Practice for Qualified Persons.¹³
- 1.13. Subject to limited exceptions, it is a requirement of the manufacturing licence that where the holder of a such a licence manufactures, assembles or imports medicinal products, they have a Qualified Person at their disposal, with the consequence that should the Qualified Person for any reason be ineligible (for example if, in the UK, the MHRA determines that they are so by reason of

¹² Implemented in the UK by Regulation 4 of the 2005 Regulations.

¹³ Produced jointly by the Institute of Biology, the Royal Pharmaceutical Society of Great Britain and the Royal Society of Chemistry, in collaboration with the MHRA and the Veterinary Medicines Directorate.

regulatory breaches), the manufacturer will be in breach of their licence if they continue to manufacture medicinal products until an eligible Qualified Person is appointed.

- 1.14. The role of a Qualified Person is, principally, to act as a quality controller for the manufacturing process of medicinal products¹⁴ and they will play a key role in ensuring that the EU Guidance on Good Manufacturing Practice is complied with.

Responsible Person

- 1.15. Under Article 79 of Directive 2001/83 and the 2005 Regulations,¹⁵ distributors are required to appoint a Responsible Person (person).
- 1.16. This person is described in the Orange Guide¹⁶ as, 'responsible for safeguarding product users against potential hazards arising from poor distribution practices as a result, for example, of purchasing suspect products, poor storage or failure to establish the bona fides of purchasers'.
- 1.17. The person should ensure that the conditions of the wholesale dealer's licence are met and that the guidelines on Good Distribution Practice are complied with. They person needs not be an employee of the licence holder but must be at his disposal, with a suitable written contract specifying their responsibilities etc. The person need not be a pharmacist, though they should have access to pharmaceutical knowledge and have personal knowledge of certain, specified matters relating to the distribution of medicines.¹⁷

¹⁴ See Article 51 of Directive 2001/83.

¹⁵ Regulation 10(1).

¹⁶ The MHRA's publication 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007' at page 355.

¹⁷ See UK Guidance on Wholesale Distribution Practice – Chapter 7 of the MHRA 'Orange Guide'.

SECTION B – REGULATION OF ADVERTISING, PRESCRIBING AND DISPENSING

Advertising

- 1.18. The regulation of the advertising of medicinal products to prescribers and those who dispense medicines seeks to prevent encouragement of the prescription or supply of a particular product. The advertisement of medicinal products to those qualified to prescribe or supply them is regulated by The Medicines (Advertising) Regulations 1994.¹⁸ Any such advertisement must contain specified information¹⁹ pertaining to the medicine in question and its use.
- 1.19. Subject to the provision of hospitality in certain circumstances, regulation 21 prohibits the supply, offer or promise of a gift in order to promote a particular product to anybody qualified to prescribe or supply it, save where the gift is inexpensive and relevant to the practice of medicine or pharmacy.²⁰
- 1.20. That same regulation also prohibits the solicitation or acceptance by a person qualified to prescribe or supply relevant medical products of any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by the regulation.²¹ In both cases, breach of the prohibition constitutes a criminal offence. Thus, prescribers are protected from improper incentives for prescribing particular medicines.
- 1.21. The Medicines and Healthcare Products Regulatory Agency has produced a guidance document (The Blue Guide) on the advertising and promotion of medicines in the UK.²²

Prescribing

- 1.22. In order, in part, to manage the NHS budget, those persons prescribing drugs do not have total freedom to prescribe as they wish. The majority of prescribers in England act under general medical services (GMS) contracts²³ and are constrained by those contracts²⁴ and, through them by reference to The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004²⁵ from prescribing at all certain drugs, medicines or other substances and other drugs save in specified circumstances. The prescribing

¹⁸ SI 1994/1932.

¹⁹ Regulation 14.

²⁰ Regulation 21(1).

²¹ Regulation 21(3).

²² See in particular

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=17736&noSaveAs=0&Revision=WEB paragraphs 6.14 to 6.17.

²³ Under Section 84 National Health Service Act 2006

²⁴ Paragraph 42 of Schedule 6 to The National Health Service (General Medical Services Contracts) Regulations 2004 SI 2004/291

²⁵ SI 2004/629 which applies only to England

habits of those who operate under a personal medical services (PMS) agreement are also constrained, by virtue of paragraph 41 of Schedule 5 to The National Health Service (Personal Medical Services Agreements) Regulations 2004,²⁶ by the same 2004 Regulations as GMS prescribers.²⁷

- 1.23. Similar provision is made in respect of Wales by the National Health Service (general Medical Services Contracts)(Prescription of Drugs Etc.)(Wales) Regulations 2004.²⁸
- 1.24. It is by virtue of those restrictions on what may be prescribed (at all or in certain circumstances) that control is exercised by the Department of Health over what drugs, medicines or other substances will and what will not be reimbursed under the NHS: if a drug cannot be prescribed (or can only be prescribed in certain cases), it cannot be dispensed (or can be dispensed only in those limited cases) and so no claim for reimbursement will be made (or claims for reimbursement will be made only in respect of those limited cases). This is subject to a certain freedom granted to pharmacists to supply a drug which appears on Schedule 1 or 2 of The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 in order to satisfy a generic or formula prescription.

Scotland

- 1.25. In Scotland, primary care is contracted by Health Boards under The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004.²⁹ Those Regulations provide,³⁰ among other things, mandatory terms which must be included in any such contract, including the essential services set out under regulation 15.
- 1.26. Schedule 5 of those Regulations sets out the other contractual terms which are required by Regulation 26. Those terms include, in Part 3, controls on what may be prescribed, in terms which are in effect similar to those in England and Wales.

NICE, ASMSG and SMC

- 1.27. The determinations of NICE, the AWMSG and the SMC also operate as constraints on prescribing practices by virtue of their analyses of the cost effectiveness of medicines and their consequent recommendations as to prescribing. More information on these bodies can be found in the OFT market study report on the Pharmaceutical Price Regulation Scheme.³¹

²⁶ SI 2004/627 which applies only to England

²⁷ See footnote 44

²⁸ SI 2004/1022, which applies only to Wales

²⁹ SSI 2004/114, made under the National Health Service (Scotland) Act 1978

³⁰ Part 5 of the Regulations

³¹ http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft885b.pdf.

Dispensing

- 1.28. The activities of pharmacists are governed, in England, by Schedule 1 of the National Health Service (Pharmaceutical Services) Regulations 2005³² and across the whole of Great Britain by the Code of Ethics for Pharmacists and Pharmacy Technicians, produced by the Royal Pharmaceutical Society of Great Britain (RPSGB).³³
- 1.29. The RPSGB is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.
- 1.30. In England, the Pharmacists and others who supply drugs pursuant to a prescription are required to dispense the drugs prescribed 'with reasonable promptness'.³⁴ The RPSGB Code of Ethics includes a requirement for 'timely access' to medicines.
- 1.31. If a branded drug is ordered / prescribed, that branded drug must be dispensed. If, however, a generic drug or formula is prescribed, it is permissible to dispense a wider range of drugs in order to meet the prescription, including a branded drug which could not actually have been prescribed. If a branded drug is prescribed to meet a generic prescription and only that branded product can meet the prescription, the pharmacist will be reimbursed the manufacturer's brand list price (minus clawback). If, however, in satisfying a generic prescription the pharmacist dispenses a branded drug where a cheaper generic could have been dispensed, the pharmacist will only be reimbursed at the Drug Tariff price (minus clawback) of the generic drug.
- 1.32. If the branded drug is unavailable from their usual supplier, pharmacists will typically try to source the medicine from a different supplier or from another pharmacist that has stock. Pharmacists may, in what is often seen as a least favoured option, have the prescription referred back to the prescriber so that, if possible, an alternative product can be prescribed.
- 1.33. As explained on the Pharmaceutical Services Negotiating Committee (PSNC) website there are, occasionally, shortages of generic products (for example, if there are manufacturing problems or a change in demand, leaving pharmacy contractors faced with dispensing an equivalent product that is only available at above the set Drug Tariff price). When this happens, PSNC is able to apply to the Department of Health for the 'No Cheaper Stock Obtainable' (NCSO) Concession

³² SI 2005/641.

³³ <http://www.rpsgb.org.uk/protectingthepublic/ethics/>.

³⁴ SI 2005/641 Schedule 1 paragraph 5(2).

to be granted for a particular month. If at the beginning of the following month the situation is not resolved, a new application is made. If this status is granted, pharmacy contractors will be reimbursed based on their endorsement rather than the fixed Drug Tariff Price. The concession is only granted where there is a licensed equivalent available and where there is a recognised stock shortage. The concession is not granted where the product is still available in the market at or below the Drug Tariff price, for example where one key wholesaler still has stock.

- 1.34. Pharmacists in Wales are subject to controls of a similar nature to those in England, though under the National Health Service (Pharmaceutical Services) Regulations 1992 (as amended), which have remained in force for that purpose.
- 1.35. No similar controls exist, however, in respect of the dispensing of drugs in hospitals. PCOs in England, for example, determine what drugs are dispensed taking account of their own local priorities and any guidance from NICE or the Secretary of State.

Key elements of the 2005 NHS Community Pharmacy Contract³⁵ for England and Wales

- 1.36. Pursuant to regulation 3 of The National Health Service (Pharmaceutical Services) Regulations 2005³⁶ (the Regulations), Schedules 1, 2 and 3 of those Regulations set out terms of service which apply, in respect of the duty on PCTs to provide pharmaceutical services, to pharmacists, doctors who provide pharmaceutical services and suppliers of appliances, respectively. The following focuses on the terms applying to pharmacists, Schedule 1.
- 1.37. Paragraph 1 of Schedule 1 provides that, insofar as they affect the rights and obligations of pharmacists, the Regulations and the Drug Tariff (insofar as it lists drugs and appliances for the purposes of s.41 of the National Health Service Act 1977 – the provision of pharmaceutical services – now s.126 National Health Service Act 2006 in respect of England), among other things, shall be deemed to form part of the terms of service for pharmacists. Similar provision is made for dispensing doctors.
- 1.38. The pharmacy contract is structured to deal with three different types of service offered by pharmacists:
 - Essential services – offered by all contractors and prescribed in Part 2 of Schedule 1 to the Regulations;

³⁵ [http://www.psn.org.uk/uploaded_txt/Public%20use%20-%20New%20Contract%20Presentation%20\(Dec%2004\).ppt](http://www.psn.org.uk/uploaded_txt/Public%20use%20-%20New%20Contract%20Presentation%20(Dec%2004).ppt).

³⁶ SI 2005/641 <http://www.opsi.gov.uk/si/si2005/20050641.htm>.

- Advanced services – intended to be provided by an increasing number of pharmacists over a transition period;
- Enhanced services – specification and value agreed nationally but the services commissioned locally by PCTs.

1.39. **Essential services:** These include:

- Dispensing – 'the supply of medicines and appliances ordered on NHS prescriptions, together with information and advice...'.³⁷
- Repeat dispensing – 'the management and dispensing of repeatable NHS prescriptions for medicines and appliances...such that the pharmacist ascertains the patient's need for a repeat supply and communicates any clinically significant issues to the prescriber'.

1.40. **Advanced services:** These are set out in Direction 3 of The Pharmaceutical Services (Advanced and Enhanced Services)(England) Directions 2005 ('the Directions') and are services for which PCTs are required to make provision. The underlying purpose of these services (medicines use review and prescription intervention services – 'MUR services') is, with the patient's agreement, to improve his knowledge and use of drugs.³⁷

1.41. **Enhanced services:** These are listed in Direction 4 of the Directions and are services for which PCTs may make provision, such as minor ailments and care home management.

Other matters relating to pharmacists

1.42. Part 3 of Schedule 1 to the Regulations contains provisions as to pharmacy opening hours. Part 4 deals with clinical governance, fitness to practice and complaints.

1.43. There are, of course, also professional rules by which pharmacists must abide. More information on this and other matters can be obtained from the website of the Royal Pharmaceutical Society of Great Britain³⁸ and of the Pharmaceutical Society of Northern Ireland.³⁹

1.44. The PSNC website⁴⁰ has some further information on the pharmacy contract and the services to be provided thereunder.

Scotland

³⁷ Direction 3(2) of the Directions.

³⁸ <http://www.rpsgb.org.uk/>.

³⁹ <http://www.psnl.org.uk>.

⁴⁰ www.psnl.org.uk.

- 1.45. Primary care is contracted by Health Boards under The National Health Service (General Services Contracts) (Scotland) Regulation 2004.
- 1.46. The provision of pharmaceutical care services (PCS) in Scotland is in the process of undergoing a radical change and differs to that in England and Wales in a number of respects. The change is part way through being implemented (by Directions made under the National Health Service (Scotland) Act 1978) and, once complete, the new pharmacy contract in Scotland will consist of four key elements:
- Minor Ailments Service (MAS)⁴¹ - under which patients who are exempt from paying prescription charges may go direct to a pharmacy for treatment, rather than a GP.
 - Acute Medication Service (AMS) - the dispensing of acute prescriptions (e.g. anti-biotics). Payment is by a flat, per item dispensing fee.
 - Public Health Service (PHS)⁴² - the display of common theme, public health messages to the public. Remuneration is calculated on the basis of the pharmacy's population 'health profile'.
 - Chronic medication process (CMS)(to go live in 2008) - a scheme for long term (e.g. 12 months), voluntary registration by a patient with a pharmacy in order that during the period of medication the patient can be helped to manage their medicine. This will facilitate the planning of care for patients by their pharmacists.
 - Additional services may be locally negotiated from an agreed national framework and tariff.

Northern Ireland

- 1.47. A new contract has not yet been agreed for Northern Ireland. Medicines management is centrally driven in Northern Ireland by the Department of Health, Social Services and Public Safety, Northern Ireland, under its Pharmaceutical Clinical Effectiveness Programme with the aim of generating high quality care for patients between primary and secondary care.

Dispensing doctors

- 1.48. Under Part 5 of the National Health Service (Pharmaceutical Services) Regulations 2005, doctors in England may be permitted to dispense prescriptions (dispensing doctors) where, principally, the rurality of the location means that a patient's needs cannot be properly met by a pharmacy. Schedule 2 of those

⁴¹ Health Board Additional Pharmaceutical Services (Minor Ailment Service) (Scotland) Directions 2007.

⁴² Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2007

same Regulations sets out the terms of service of such dispensing doctors. Insofar as is relevant, those terms of service are similar to those for pharmacists in Schedule 1, in particular the requirement to supply the drug prescribed (notably a particular branded drug if that is what is ordered) with reasonable promptness.⁴³ Of course, a dispensing doctor will, in ordering, be aware of their own stocks of medicines.

- 1.49. Similar arrangements can be made in Scotland. Part 3 of Schedule 5 to The National Health Service (General Medical Services Contracts)(Scotland) Regulations 2004 makes provision for prescribing and dispensing activities. Among other things, power is given by paragraph 44 of that Part for Health Boards to contract for the provision of dispensing services by doctors where, principally, the rurality of the location means that the needs of a patient cannot be properly met by a pharmacist.

⁴³ SI 2005/641 Paragraph 3(2) of Schedule 2.

SECTION C – PRICING AND REIMBURSEMENT

C.1 - THE PPRS⁴⁴

1.50. The PPRS is the means by which the Department of Health seeks to constrain the prices of branded medicines paid for by the NHS. The PPRS is not a formal regulatory system, nor does it control prices directly. Rather, it is a voluntary arrangement under sections 261 to 268 of the National Health Service Act 2006 between the Department of Health and pharmaceutical industry as represented by the Association of the British Pharmaceutical Industry (ABPI). In the absence of such an arrangement, a statutory scheme can, under the National Health Service Act 2006, be put in place.

1.51. The stated objectives of the PPRS are to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices.
- Promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines.
- Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

1.52. The scheme comprises two key components:

- The profit cap (of 29.4 per cent return on capital) and floor (of 8.4 per cent return on capital): This applies to all the branded products sold by a company to the NHS and associated features (e.g. cost allowances for certain types of expenditure such as R&D expenditure); and
- A range of price controls: There is freedom to set the initial price of new active substances (NAS) but restrictions on subsequent increases to the list price; controls on the pricing of non-NAS; and the one-off price cuts periodically agreed at the time of scheme renegotiations.

1.53. The PPRS price and profit controls relate to the entire portfolio of branded medicines (both in- and out-of-patent) sold by a medicines manufacturer to the NHS. Annexe D discusses the price cut mechanism of the PPRS in so far as it affects financial flows between pharmacies and the Department of Health.

1.54. Despite its name, the scheme is not a truly regulatory mechanism (i.e. one that constrains commercial relations between two third parties) but represents an

⁴⁴ See also Annexe G to the OFT PPRS market study report
http://www.of.gov.uk/advice_and_resources/resource_base/market-studies/price-regulation

attempt to exercise buyer power in the purchase of prescription pharmaceuticals by the NHS across the UK.

GlaxoSmithKline v Department of Health

1.55. On 21 June 2007, the High Court handed down a judgment in a case arising out of dispute between GlaxoSmithKline and the Department of Health, pertaining to the 1999 PPRS and the extent to which it bound the parties to more than its explicit terms. The dispute centred on the question:

'whether under the terms of the 1999 PPRS, GlaxoSmithKline (GSK) was prohibited from including volumes of sales of products sold to fulfil generic prescriptions in the calculation of list price reduction that it had delivered'.

1.56. It should be noted that the provision of such information was specifically addressed in the 2005 PPRS⁴⁵ which explicitly prohibits companies from including brand equalisation volumes for the purpose of modulating prices under that scheme.

1.57. The court was unconvinced by the claims of the DH that the 1999 PPRS did not create or identify legal rights and liabilities but that even if it did, it should be interpreted so as to give effect to the intention of the parties, as claimed by the DH, that the effect of the price cut and modulation was to achieve an overall saving to the NHS of 4.5 per cent. The DH's alternative claim, that the earlier award in the dispute of the Arbitration Panel implied a term to similar effect, was also rejected.

1.58. The court went on to state that GSK focused on all the references to price reduction and pointed out the absence of any reference to the saving of cost to the NHS while the DH stressed the underlying objective as seen by the NHS of achieving such savings. In his reasoning for rejecting the position of the DH, the judge explained that:

'It is accepted by all that it is impossible to calculate the net savings achieved by the NHS in the event of a list price reduction, because of the knock on effect of this upon others involved in the market'.⁴⁶

1.59. The Court in this case made it clear that the PPRS is a contract and the parties will be hard pressed to have implied into it anything which it does not expressly contain in its terms.

⁴⁵ Paragraph 26.3.

⁴⁶ Paragraph 53 of the judgment.

C.2 – DRUG TARIFFS AND REIMBURSEMENT

1.60. The relevant Drug Tariff (one each for England and Wales, Scotland and Northern Ireland) sets out the price at which, among other things, medicines supplied under the NHS will be reimbursed.

England & Wales

- 1.61. Section 129 of the National Health Service Act 2006 requires that Regulations must be made in order, essentially, that Primary Care Trusts and Health Authorities can deliver to patients their services and that patients can receive the drugs prescribed for them by, for example, their GP. Section 164 of that Act makes provision for the remuneration of those providing pharmaceutical services.
- 1.62. Regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005 provides for the creation of the Drug Tariff for the determination of payments to chemists.
- 1.63. In respect of Wales, power to compile the Drug Tariff comes from regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992, which makes similar provision to regulation 56 of the 2005 Regulations quoted above. The 1992 Regulations have been repealed in respect of England but remain in force for Wales.
- 1.64. Pursuant to regulation 56(1)(d) above, Clause 7 of the Drug Tariff provides that reimbursement of drugs supplied under the NHS is calculated on the basis of a 'basic price' which, for those drugs listed in Part VIII of the Drug Tariff (generic drugs), is the price listed alongside those drugs in that Part (Drug Tariff Clause 8A). Clause 8B provides that, in exceptional circumstances of shortage of supply, claims for reimbursement at a higher value may be made.
- 1.65. Clause 8C of the Drug Tariff provides, in respect of drugs not listed in Part VIII (namely branded drugs), that the basic price shall be the list price. In the absence of such a list price, the basic price for a branded drug shall be determined by the Secretary of State for Health and the National Assembly for Wales.
- 1.66. Clause 6 of the Drug Tariff for England and Wales identifies that for the purposes of reimbursement, from the basic price is deducted an amount taken from a Deduction Scale at Part V of the Tariff, which is a scale of percentages increasing along with the increasing monthly total of sales of an applicant. This is commonly referred to as the 'clawback' and is intended to represent the discount that a pharmacist might be expected to get for their supplies of drugs.⁴⁷

⁴⁷ See Annexe D for more information on Category M and the clawback.

- 1.67. The Drug Tariff (notably the Part VIII basic prices, in particular Category M – drugs which are readily available) for England and Wales is amended periodically (Category M typically quarterly) by administrators on behalf of the Secretary of State, pursuant to Regulation 56(1).
- 1.68. These adjustments are made in order that the retained buying profit, agreed for between Government and the PSNC for the year 2006/2007 at £500 million for England, can be achieved.

Scotland

- 1.69. Regulation 9 of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995, made under section 27 of the National Health Service (Scotland) Act 1978, makes similar provision in respect of Scotland. The Scottish Drug Tariff, like that for England and Wales, is amended monthly.

Northern Ireland

- 1.70. In respect of Northern Ireland, regulation 9 of the Pharmaceutical Services Regulations (Northern Ireland) provides for the creation and updating of the Drug Tariff. This is done by the Department of Health, Social Services and Public Safety.

SECTION D – APPLICATION BY WHOLESALERS FOR INTERIM INJUNCTION AGAINST THE IMPLEMENTATION OF PFIZER'S DIRECT TO PHARMACY SCHEME

- 1.71. Towards the end of February 2007, a number of wholesalers issued in the High Court an application for interim injunctions against Pfizer Ltd (with UniChem Ltd subsequently joined as the second defendant) to restrain Pfizer from terminating its supply agreements with them and from refusing to supply them with its prescription medicines, as a part of its switch to its direct to pharmacy distribution model. It was claimed that such termination and refusal would infringe Articles 81 and 82 EC Treaty and the corresponding prohibitions in chapters 1 and 2 of the Competition Act 1998. The claim was brought with the support of a number of trade bodies and associations, including the National Pharmaceutical Association (NPA), the Pharmaceutical Services Negotiating Committee (PSNC), the Independent Pharmacy Federation (IPF) and the Dispensing Doctors Association (DDA).
- 1.72. On 2 March 2007 the High Court rejected the application for an interim injunction, after balancing the risks of injustice if the injunction is made or refused.
- 1.73. The High Court also criticised the wholesalers' delay in making the application. The claimants explained that they had delayed applying to the High Court for an interim injunction pending a decision from the OFT on their complaint lodged on 1 November 2006 alleging breaches of the same prohibitions and on their request that the OFT impose interim measures. At the time that the application for an interim injunction was made, the OFT had made no decision on the application for interim measures, nor had it concluded whether or not the threshold under the Competition Act 1998 was met in order to commence an investigation under the Competition Act 1998. Soon after the application, the OFT informed the claimants that even if it were open to it to impose interim measures, it would not do so because there was insufficient evidence of irreparable harm.
- 1.74. While the High Court acknowledged that it was entirely appropriate for the claimants to complain to the OFT, this should not have delayed, to the extent that it did, their application to the Court for an injunction, having been knowledgeable of the plans of Pfizer and UniChem for some months.