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EXECUTIVE SUMMARY

The Pharmaceutical Price Regulation Scheme (‘PPRS’) is a voluntary scheme between the UK Departments of Health and the Association of the British Pharmaceutical Industry, within the terms currently of section 33 of the Health Act 1999. From 1 March 2007, section 261 of the National Health Service Act 2006 will be the relevant provision under which the scheme is recognised and is identical to the existing provision.

Relevant powers may be exercised by the Secretary of State where a voluntary scheme exists for the purpose of limiting the prices which may be charged by a manufacturer, or supplier, for the supply of health service medicines, or of limiting the profits of a manufacturer or supplier in relation thereto.

In the absence of a voluntary scheme or in relation to those manufacturers or suppliers who are not members of a voluntary scheme / the PPRS, section 35 of the Health Act 1999 (and from 1 March 2007 section 263 NHS Act 2006) gives the Secretary of State power to make a statutory scheme for similar purposes to a voluntary one.

Whereas, under devolution, many health matters are devolved to the different administrations, powers under sections 33 to 38 Health Act 1999 / sections 261 to 266 NHS Act 2006 are exercisable by Westminster in respect of the whole of the UK. This means that co-ordination would be required in order that powers under devolved health matters which are pertinent to recommendations for reform made in the report, can be used in ways which would ensure a consistent and workable reform UK wide.

The various Drug Tariffs compiled throughout the UK (one for England and Wales, another for Scotland and another for Northern Ireland) are made under powers granted in order that health services can be provided to patients. The various tariffs set, among other things, the amount that pharmacies and others will be reimbursed for drugs supplied under the national health systems of the UK.

In compiling the Drug Tariffs and any legislation which restricts the use or reimbursement of drugs within the scope of the national health systems, regard must be had to Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion on the scope of national health insurance systems (‘the Transparency Directive’). That Directive contains provisions as to a number of procedural requirements relating to the pricing and reimbursement decisions by Member States’ in relation to medicinal products included in the scope of their social security systems (for example, time periods within which decisions must be made and high level criteria by which those decisions must abide). With regard to the PPRS, Article 5 of the Directive is the most significant, requiring as it does information to be sent to the European Commission concerning profitability controls imposed by Member States on suppliers of medicinal products. Litigation under the Transparency Directive typically relates to the failure of Member States’ competent bodies to abide by the high level procedural controls which it sets out.
In England, Wales and Scotland, there exist bodies which are of particular importance to this market study. (The National Institute for Health and Clinical Excellence (NICE) in England, the Scottish Medicines Consortium (SMC) in Scotland and the All Wales Medicines Strategy Group (AWMSG) in Wales). No similar body exists in Northern Ireland. NICE is a Special Health Authority, established under legislation, which produces for England guidance on the promotion of good health and the prevention of ill health, on clinical practice and, most relevant to this market study, on the use of new and existing medicines, treatments and procedures within the NHS. SMC is a committee of the 14 Health Boards of Scotland which produces guidance for Scotland on the clinical and cost effectiveness of medicines. The AWMSG is an expert group, recognised under legislation, which provides advice to the Welsh Assembly in relation to strategic developments in prescribing.

There are many detailed controls which apply to the activities of prescribing and dispensing drugs. In the context of this market study, the most relevant are those which restrict what can actually be prescribed and the provisions by virtue of which those dispensing drugs for reimbursement under the NHS are obliged to dispense according to the prescription.

At a higher level of application, regard must also be had to European Community rules prohibiting the granting of illegal state aid (Article 87 EC Treaty) and to domestic (Competition Act 1998) and EC (Articles 81 and 82 EC Treaty) rules on competition law. European Community rules on the free movement of goods (Articles 28-30 EC Treaty) are also relevant but, in pharmaceutical drugs markets, now typically arise in the context of disputes based on competition law.
1 INTRODUCTION

1.1 This annexe outlines the legal framework within which the Pharmaceutical Price Regulation Scheme ('PPRS') exists. It is divided into seven sections:

- UK legislation relevant to pharmaceutical pricing
- NICE, SMC, AWMSG and SIGN
- prescription and dispensing
- drug Tariffs and reimbursement
- EC law: pricing and reimbursement – transparency directive
- EC law: state aid, and
- competition law.

1.2 This annexe provides an overview only. For further detail, refer to the full copies of the relevant UK legislation, in particular the Health Act 1999 ('the 1999 Act') and the National Health Service Act 2006,¹ and the relevant EC legislation and case law.²

1.3 Some of what follows is taken from the Explanatory Notes to the 1999 Act.³

¹ Copies of which are available at http://www.opsi.gov.uk/legislation/
² Copies of which are available at http://europa.eu.int/
2 UK LEGISLATION RELEVANT TO PHARMACEUTICAL PRICING

Introduction

2.1 The statutory background to the PPRS is sections 33 – 38 of the 1999 Act. From 1 March 2007, those provisions will be replaced by sections 261 to 268 National Health Service Act 2006. As the Health Act 1999 is currently in force, it is those provisions to which reference is made in this annex. Section 33 provides powers in connection with which the PPRS, as a voluntary (profit control) scheme, is made. Sections 34 and 35 give the Secretary of State powers to control health service medicine prices and make a statutory price or profit control scheme if no voluntary scheme applies. In other words, the possibility of legislative controls backs up the voluntary scheme and the powers that exist in relation to it.

2.2 The PPRS itself has operated in various forms since 1957. In its present form it controls pharmaceutical companies’ profits from the sale of branded prescription medicines to the NHS throughout the UK. It is a voluntary, non-statutory agreement between the Department of Health (and the devolved administrations’ health departments – see Devolution below), and the pharmaceutical industry represented by the Association of the British Pharmaceutical Industry (ABPI).

2.3 Section 57 of the National Health Service Act 1977 Act (the 1977 Act) enabled the Secretary of State by order to control maximum prices for medical supplies. It did not, however, provide powers to regulate profits. Accordingly, it could not be used to ensure compliance by pharmaceutical companies with all elements of the PPRS as a profit control scheme. Sections 33 – 38 of the 1999 Act addressed this shortcoming (and section 38(5) says section 57 of the 1977 Act no longer applies to health service medicines). Section 260(1) of the NHS Act 2006 contains a provision to similar effect, which states that:

‘The Secretary of State may by order provide for the control of maximum prices to be charged for any medical supplies, other than health service medicines, required for the purposes of this Act.’

The 1999 Act provisions

2.4 The 1999 Act makes provision for two different types of scheme: a voluntary scheme and a statutory scheme. The former scheme is made by agreement between the Secretary of State and the industry body, as described below, whereas the latter can be created unilaterally by the Secretary of State after consultation with the industry.

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4 References to statutory provisions in the ‘UK Legislation’ section of this annex are to provisions of the 1999 Act unless otherwise stated.
body. A statutory scheme may not apply to a manufacturer or supplier to whom a voluntary scheme applies.\textsuperscript{5}

2.5 'Industry body' is defined in the Act\textsuperscript{6} as:

‘...any body which appears to the Secretary of State appropriate to represent manufacturers and suppliers’.

2.6 In practice, this is the Association of the British Pharmaceutical Industry (ABPI). The Act refers to ‘the’ industry body, which on a narrow, literal interpretation suggests that only one body could be a party to the voluntary scheme or be consulted for the purpose of a statutory scheme. We are not aware that the issue of a second industry body being involved has ever arisen.

**Section 33 Voluntary scheme**

2.7 As the 2005 PPRS makes clear, it is an agreement for the purposes of section 33 of the 1999 Act.

2.8 **Section 33** enables the Secretary of State, after making a scheme with the industry body (in practice the ABPI), to make regulations or issue directions to secure compliance with certain key elements of that scheme. Such a scheme (with additions or modifications agreed in individual cases) only applies to those companies who consent (subsection (2)).

2.9 Subsections (4) and (5) provide for the Secretary of State to give notice to a manufacturer or supplier that the scheme is no longer to apply to him. This can be done where the actions or omissions of the manufacturer or supplier have shown the scheme is ineffective in his case. Subsection (6) read with section 38 enables the Secretary of State by regulations or direction to specify how consent to a scheme, under subsection (2)(a), must be given or withdrawn.

2.10 Subsection (7) read with section 38 gives the Secretary of State power by regulations or direction to require any manufacturer or supplier to record and keep information, and to provide that information to the Secretary of State.

2.11 **Section 33(8)** read with section 38 enables the Secretary of State by regulations or directions to prohibit any manufacturer or supplier to whom the scheme applies from increasing the prices of medicines provided to the health service without the Secretary of State’s approval and, where this is breached, provides for payment of any excesses representing the increase to the Secretary of State within a specified period.

\textsuperscript{5} Section 35(7)
\textsuperscript{6} Section 38(6)
Sections 34 – 36 Statutory scheme

2.12 In addition to powers to secure compliance with a voluntary scheme, the 1999 Act provides powers to control maximum prices of health service medicines in other circumstances and to provide for a statutory scheme limiting prices or profits.

2.13 **Section 34** read with section 38 provides for the Secretary of State, after consultation with the industry body, by regulations or direction, to limit any price which may be charged by any manufacturer or supplier of any health service medicine and for payment of the excess to the Secretary of State within a specified period. This power is only exercisable in relation to companies who are not members of a voluntary scheme, as defined in section 33(4). Section 34 replaces section 57 of the 1977 Act with respect to controlling the maximum price of health service medicines. Section 38(5) therefore provides that section 57 of the 1977 Act shall cease to have effect in relation to health service medicines (but the powers in sections 33 – 36 do not affect any other powers of the Secretary of State to control profits or prices).

2.14 **Section 35** read with section 38 enables the Secretary of State, after consultation with the industry body, by regulations or direction to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines. Section 35(3) provides that such a scheme may in particular require any manufacturer or supplier to whom it applies to record and keep information and provide information to the Secretary of State. Section 35(5) provides for payment to the Secretary of State of profits in excess of the limits determined under any statutory scheme. Section 35(6) enables the Secretary of State to prohibit any manufacturer to whom such a scheme applies from increasing prices without his approval and to require a sum representing the amount of that excess to be paid to him. Section 35(7) provides that a statutory scheme will not apply to members of a voluntary scheme (‘scheme members’ as defined in section 33(4)).

2.15 **Section 36** read with section 38 gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions enabling or facilitating the introduction of a statutory scheme.

Section 37 Enforcement of a scheme

2.16 **Section 37** provides for enforcement. Section 37(1) enables the Secretary of State to make regulations providing for the payment of penalties by a person who contravenes any provision of regulations or directions made under sections 33 to 36. Section 37(2) provides that the maximum single penalty for which provision can be made is £100,000 and the maximum daily penalty is £10,000. Section 37(3) provides that amounts payable to the Secretary of State in respect of excessive prices can be increased by up to 50 per cent. Section 37(4) enables the Secretary of State to provide that the amount payable to him will carry interest at a rate specified or referred to in the regulations. Sums payable to the Secretary of State are recoverable through the civil courts.
2.17 Section 37(5) enables provision to be made by regulations conferring on suppliers and manufacturers a right of appeal against enforcement decisions. Section 37(7) defines the enforcement decisions against which a supplier or manufacturer may appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information to him, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier, or (d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him.

2.18 Section 37(8) provides that any requirement, prohibition or limit under sections 33 to 36 may only be enforced under this section and not relied on in any other proceedings. Section 37(9) requires the Secretary of State to consult the industry body before making regulations under section 37. Section 37(10) provides for the maximum penalties set out in section 37(2) to be increased by order, subject to the affirmative resolution procedures as provided for in section 62(8).

Section 38

2.19 Section 38 deals with supplementary matters. In particular, section 38(1) provides how the powers in sections 33(6) to (8) and 34 to 36 may be exercised, namely by regulations or, in the case of a particular manufacturer or supplier, by directions, and that regulations may give power to the Secretary of State to make directions in such particular cases. Section 38 provides that the power to control prices and profits may be exercised only with a view to limiting them to what is fair and reasonable and for the purposes of the health service. The Secretary of State and any other person must bear in mind the need for medicinal products to be available to the health service on reasonable terms and the costs of research and development.

Supplementary regulations

2.20 Supplementary regulations have been made under the powers contained in sections 33 – 38 of the 1999 Act.

2.21 Under section 33(6) regulations have been made setting out the manner in which a manufacturer or supplier of health service medicines is required to consent (or withdraw consent) to a voluntary scheme being treated as applying to it.  

2.22 Regulations have also been made under sections 34(1), 36, 37(1) to (5) and (9) and 38(1) to control the price of branded medicines sold for national health service purposes where:

- marketing authorisations have been granted for that medicine, and

— The Health Service Medicines (Consent to Voluntary Scheme) Regulations 1999, SI 1999/2229
• it is supplied by a company which is not a voluntary scheme member within the meaning of section 33(4).  

2.23 These regulations set out a mechanism by which the maximum price for such medicines is set. They also require information on the sales of branded health service medicines to be kept, and where the Secretary of State so directs, supplied to him. Provision is also made for enforcing the regulations (by recovery of prices charged in excess of the maximum and paying interest on outstanding sums, the recovery of penalties and appeals against decisions made thereunder). The provisions in relation to appeals are themselves supplemented by further, more detailed, regulations made under sections 37(5) and (6).  

2.24 Similar regulations have also been made under the same powers in respect of certain generic medicines sold for the purpose of the National Health Service (which are not covered by the voluntary PPRS scheme). Separate regulations, again using most of the same powers, have been made in respect of the provision of information to the Secretary of State in relation to the price of certain specified generic medicines sold for the same purpose. Certain manufacturers and wholesalers are required to provide information to the Secretary of State on the volume of sales and supplies. Provision is made for daily penalties for non-provision of information and for appeals against decisions under the regulations.

Devolution and the PPRS

Introduction

2.25 Certain matters relating to health are devolved to the administrations in Scotland, Wales and Northern Ireland. However, these do not extend to the statutory powers in sections 33 – 38 of the 1999 Act. Those powers remain exercisable by the Secretary of State for the whole of the UK (even though the PPRS itself is entered into by both the DH and the devolved health administrations). This will remain the position under the National Health Service Act 2006.  

Sections 33 – 38 and 68 of the 1999 Act

2.26 Section 68 of the 1999 Act makes clear that its sections 33 to 38 apply to England, Scotland, Wales and Northern Ireland. Accordingly, the Secretary of State is able to

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8 The Health Service Medicines (Control of Prices of Branded Medicines) Regulations 2000, SI 2000/123  
10 Health Service Medicines (Control of Prices of Specified Generic Medicines) Regulations 2000, SI 2000/1763  
11 The Health Service Medicines (Information on the Prices of Specified Generic Medicines) Regulations 2001, SI 2001/3798  
12 Though as from 14 October 2002 the Northern Ireland Assembly and Executive have been suspended  
13 Sections 271(3) and 278(3) National Health Service Act 2006
make regulations in respect of each part of the UK. The various devolution settlements reflect this.

**Scotland**

2.27 In relation to Scotland, by virtue of sections 29, 30 and Section J4 of Part II to Schedule 5 to the Scotland Act 1998, the,

'Regulation of prices charged for medical supplies or medicinal products which (in either case) are supplied for the purposes of the health service established under section 1 of the National Health Service (Scotland) Act 1978 [is a] reserved matter.'

The Scottish Executive does not therefore have powers in relation to it. Rather, such powers are reserved to Westminster and, in relation to sections 33 – 38 of the 1999 Act, to the Secretary of State.

**Wales**

2.28 Health matters generally are devolved to the National Assembly for Wales. So, under Article 2 and Schedule 1 of The National Assembly for Wales (Transfer of Functions) Order 1999 SI1999/672 the Assembly is given power to exercise in relation to Wales a wide range of health functions, including certain powers to make secondary legislation (statutory instruments – regulations and orders) that are contained in the 1999 Act. However, the same parts of that Order specifically provide that the powers to make such legislation contained in sections 33 – 38 of the 1999 Act are not devolved in relation to Wales. They remain with the Secretary of State.

**Northern Ireland**

2.29 Since the Northern Irish Assembly and Executive were suspended on 14 October 2002, the position, for the time being, is that the powers in sections 33 – 38 of the 1999 Act are exercisable by the Secretary of State unaffected by devolution issues. On any restoration of the Assembly and Executive, the position would be as follows.

2.30 Under the Northern Ireland Act 1998 matters are either expressly 'excepted' or 'reserved' (see section 4(1) and Schedules 2 and 3). If a matter is neither excepted nor reserved it is transferred (section 4(1)). Speaking broadly, the Northern Irish Assembly:

- cannot legislate on excepted matters
- can only legislate on reserved matters with the Secretary of State’s consent, but
- is free to legislate on transferred matters.

14 Made under the Government of Wales Act 1998
2.31 By virtue of section 5(6) of the Northern Ireland Act 1998 the UK Parliament also has the power to legislate on transferred matters. In practice, the convention has been that Westminster would obtain the Assembly’s consent before it exercises that power.

2.32 The operation of a pharmaceutical price regulation scheme, and the powers in sections 33 – 38 of the 1999 Act, are (or would be) transferred matters. So, when the Northern Irish Assembly is in operation, they are matters on which the Assembly has competence but on which the Secretary of State may also act. In practice, the latter would do so with the former’s consent.
3 NICE, SMC, AWMSG AND SIGN

England - NICE

3.1 NICE, the National Institute for Health and Clinical Excellence, exercising functions pursuant to sections 16(2) and 126(4) of the National Health Service Act 1977, was established as a legal entity under section 11 of that Act 1977 by The National Institute for Clinical Excellence (Establishment and Constitution) Order 1999, which came into force on 26 February 1999.

3.2 Section 11 National Health Service Act 1977:

'Special Health Authorities

(1) The Secretary of State may by order establish special bodies for the purpose of exercising any functions which may be conferred on them by or under this Act

(2) The Secretary of State may, subject to the provisions of Part III of Schedule 5 to this Act, make such further provision relating to that body as he thinks fit

(3) A body established in pursuance of this section shall (without prejudice to the power conferred by subsection (4) below allocate a particular name to the body) be called a Special Health Authority…'.

3.3 NICE is a Special Health Authority and was created to perform, as provided by Article 3 of the above named Order (as amended by the National Institute for Clinical Excellence (Establishment and Constitution) Amendment Order 2005):

'(a) such functions in connection with the promotion of clinical excellence, and the effective use of available resources in the health service

(b) such functions in connection with the promotion of excellence in public health provision and promotion and in that connection the effective use of resources available in the health service and other available public funds

(c) such other functions

as the Secretary of State may direct.'

3.4 NICE’s remit covers the following areas of health:

- advice on clinical practice, in the form technology appraisals (covering England and Wales, and Scotland for part of its output)
- interventional procedures (covering the whole of the UK)
- clinical guidelines (in England and Wales)

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15 See Annex B for a review of NICE, SMC and AWMSG, the cost effectiveness bodies covering England, Wales and Scotland
16 To be replaced by section 28 National Health Service Act 2006 from 1 March 2007
17 SI 1999/220
18 SI 2005/497
• guidance from two separate programmes on effective public health practice (covering England).

3.5 On 31 March 2005, Directions and Consolidating Directions were issued to NICE which included the following:

‘Functions of the Institute

‘2.—(1) The Secretary of State directs the Institute to exercise the following functions in connection with the promotion of clinical excellence and the effective use of available resources in the health service—

(a) to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State and to make recommendations.’

3.6 It is the technology appraisals\(^{20}\) of NICE, under (a) above, which are relevant to the PPRS dealing as they do with, among other things, medicines. It should be noted that it is those Directions also which provide that NICE is to assess those health care interventions of which the Secretary of State notifies it.

3.7 On 1 July 2003, the Secretary of State for Health issued Directions\(^{21}\) under the NHS Act 1977, to Primary Care Trusts and NHS Trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from NICE. The Directions, which apply only to England, provide that subject to specified exceptions;

‘2. …a Primary Care Trust shall, unless directed otherwise by the Secretary of State, in exercising those functions that it has been directed to exercise by the Secretary of State, apply such amounts of the sums paid to it under section 97C(1)(b) of the [National Health Service] Act [1977] as may be required to ensure that a health care intervention that is recommended by the Institute [NICE] in a Technology Appraisal Guidance is, from a date not later than three months from the date of that Technology Appraisal Guidance, normally available:

(a) to be prescribed for any patient on a prescription form for the purpose of his NHS treatment; or

(b) to be supplied or administered to any patient for the purpose of his NHS treatment.’

3.8 It is only by virtue of those Directions that the guidance of NICE can be said in any way to bind those whom it concerns.

\(^{19}\) Technology appraisals issue guidance on the use of new and existing medicines and treatments. Intervventional procedures issue guidance on whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. Clinical guidelines issue guidance on the appropriate treatment and care of people with specific diseases.

\(^{20}\) A brief description can be found on the NICE website at http://www.nice.org.uk/page.aspx?o=202425

3.9 The All Wales Medicines Strategy Group (AWMSG) is an advisory committee which is established and recognised in accordance with section 2 of and Schedule 6 to the NHS Act 1977.22

3.10 Its members are appointed by the Minister for Health and Social Services on behalf of the Welsh Assembly Government, following nominations from appropriate representative committees (for example, a consultant in public health, a general practitioner with a prescribing lead, a chief pharmacist from an NHS Trust, a health economist etc).

3.11 The AWMSG provides advice to the Welsh Assembly Government in relation to strategic developments in prescribing, including: the provision of timely, independent and authoritative advice on new drugs and the cost implications of making these drugs routinely available on the NHS in Wales; advice on the development of a prescribing strategy for Wales; advice on the implementation of a range of strategic task and finish group recommendations, etc.

3.12 As stated in a paper published by the National Assembly in June 2006, providing background on the process which drugs and medicines are licensed, regulated and approved for use in the health service in Wales, England and Scotland:23

‘3.1 The AWMSG provides interim recommendations to the Welsh Minister for Health and Social Services on medical products based on clinical and cost-effectiveness data, prior to the publication of NICE guidance... The Group also advises the Minister in a strategic and advisory capacity on future developments in healthcare, to inform strategic planning. The AWMSG takes into account the NICE future work programme when considering whether to appraise a product, and will not normally consider a product if NICE intends to publish a final appraisal of that product within 18 months;

3.22 Pharmaceutical companies are required to notify the AWMSG of details of all new products and medications before being launched, which allows the Group to make a recommendation soon after the product is launched. If a drug or medicine is supported by the AWMSG and is approved by the Minister, LHBs and NHS Trusts in Wales must make funding available within three months of notification of the ministerial decision. Similarly, LHBs and NHS Trusts in Wales must implement NICE Technology Appraisals within three months of publication, although in exceptional circumstances the Welsh Assembly Government has extended the timescale for implementation.’


23 http://www.wales.gov.uk/keypubmrs/content/06-028.pdf
3.13 Recommendations are made by the AWMSG on the use of high cost medicines (those with a potential cost of over £2,000 per patient per year) to the Minister for Health and Social Services who will ratify the recommendations, if accepted.

3.14 In respect of NICE, a Special Health Authority exercising functions under sections 16(2) and 126(4) of the National Health Service Act 1977, as identified in footnote 1 to SI 2002/1759, the functions of the Secretary of State under that section were, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2(a) of the National Assembly for Wales (Transfer of Functions) Order 1999\(^\text{24}\) as amended. Functions under sections 16(2) and 126(4) of the National Health Service Act 1977, in relation to NICE, are by their nature exercisable concurrently by the Secretary of State and the National Assembly for Wales by virtue of article 2(c) of the 1999 Order.

**Scotland - SMC**

3.15 In Scotland the Scottish Medicines Consortium (SMC), a body comprised of representatives of the 14 Health Boards of Scotland sitting together as the SMC under the umbrella of NHS Quality Improvement Scotland, advises NHS Area Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland on the clinical and cost effectiveness of:

- all newly licensed medicines
- all new formulations of existing medicines
- all new conditions that the medicines will treat (licensed from January 2002).\(^\text{25}\)

3.16 As set out in a letter from the Health Department,\(^\text{26}\) under the heading 'National Implementation Planning':

'9. Unique category drugs recommended by SMC must be made available uniformly across Scotland. The executive cohort on SMC will agree a national implementation plan for these products. Normally, these drugs will be provided to meet clinical need within 3 months of publication of the SMC advice. However, this implementation period may be varied due to restrictions in the SMC advice, for example, where there is a requirement to establish an audit. All NHS Boards will be required to follow the national implementation plan for these drugs.'

3.17 There is no legal requirement on manufacturers to provide SMC with data in order that products can be assessed. It is understood that the benefits of having an SMC assessment of a product, in light in particular of the paragraph quoted above, provides the incentive.

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\(^{24}\) SI 1999/672

\(^{25}\) Taken from the NHS Quality Improvement Scotland website http://www.nhshealthquality.org

\(^{26}\) NHS HDL (2003) 60 of 25 November 2003
3.18 NHS QIS gives advice on implications for Scotland arising from guidance produced by NICE. Health Department letter HDL(2006) 29 of 12 May 2006 explains the interaction between NICE Single Technology Appraisals (STs) of drugs already evaluated by the SMC:

‘3. In most cases, there will be no material difference between NICE and SMC recommendations. However, if they differ, we expect NHS boards to continue to comply with the SMC advice because of the robustness of the SMC process and its wide recognition and acceptability within NHS Scotland. If a NICE STA endorses a drug that was not recommended by the SMC, it would be open to the manufacturers to resubmit the drug to SMC with new evidence. NHS QIS will remind the NHSScotland of the SMC recommendation on the day of a NICE STA release.’

3.19 In respect of NICE Multiple Technology Appraisals (MTAs), HDL (2006) 29 states that:

‘4. NHS QIS will continue to provide advice via email to NHSScotland on the NICE MTA on the day of release. Where NHS QIS decides that an MTA should apply in Scotland, their recommendations supersede SMC advice.’

SIGN

3.20 The Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993 by the Academy of Royal Colleges and their Faculties in Scotland, to develop evidence-based clinical guidelines for the National Health Service (NHS) in Scotland. In January 2005, it became a part of NHSQIS, as is also the SMC. As stated on the NHSQIS website, the objective of SIGN is:

‘to improve the quality of healthcare for patients by reducing variation in clinical practice and clinical outcome, through the development and dissemination of national guidelines containing recommendations for effective practice based on current evidence.’

4 PRESCRIPTION AND DISPENSING

4.1 What follows is a very brief description of limited aspects of each of prescribing and dispensing drugs, which are most relevant to the PPRS market study. The regimes governing these activities are very detailed but it is unnecessary to go into more detail in this annexe.

Prescription

4.2 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) contracts and are constrained by those contracts and, through them by reference to The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 from prescribing at all certain drugs and other drugs save in specified circumstances. The prescribing habits of those who operate under a personal medical services (PMS) agreement are also constrained, by paragraph 41 of Schedule 5 to The National Health Service (Personal Medical Services Agreements) Regulations 2004, by the same 2004 Regulations as GMS prescribers. Those Prescription of Drugs Regulations provide, among other things, that:

2. A drug, medicine or other substance listed in Schedule 1 may not be ordered for patients in the provision of medical services under a general medical services contract.

3. A drug, medicine or other substance specified in an entry in column 1 of Schedule 2 may not be ordered for a patient in the provision of medical services under a general medical services contract unless –

(a) that patient is a person of a description mentioned in column 2 of that entry; and

(b) that drug, medicine or other substance is prescribed for that patient only for the purpose specified in column 3 of that entry.'

4.3 Similar provision is made in respect of Wales by the National Health Service (general Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004. In some cases, for example in respect of Viagra, a Health Circular is issued by the

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28 Under Section 28Q National Health Service Act 1977 and from 1 March 2007 section 84 National Health Service Act 2006
29 Paragraph 42 of Schedule 6 to The National Health Service (General Medical Services Contracts) Regulations 2004 SI 2004/291
30 SI 2004/629 which applies only to England
31 SI 2004/627 which applies only to England
32 See footnote 44
33 SI 2004/1022, which applies only to Wales
34 UK (R (on the application of Pfizer Ltd.)) v. Secretary of State for Health [2003] 1CMLR 19 – HSC 1998/158
Secretary of State for Health containing interim guidance to prescribers about prescribing a particular drug.

4.4 It is by virtue of those restrictions on what may be prescribed (at all or in certain circumstances) that control is exercised by government over what drugs 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 (see paragraph 4.9 below).

4.5 Subject to the provision of hospitality in certain circumstances, regulation 21 of The Medicines (Advertising) Regulations 1994 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.

4.6 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. In both cases, breach of the prohibition constitutes a criminal offence, though an offence committed by the promoter of a product carries a greater penalty than that to which a qualified prescriber or supplier is liable.

4.7 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.

Dispensing

4.8 Pharmacists and others who supply drugs pursuant to a prescription are required to dispense the drugs prescribed:

8. — Providing ordered drugs or appliances

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35 SI 1994/1932
36 Regulation 21(1)
37 Regulation 21(3)
38 Regulation 23(1)
39 Regulation 23(2)
40 See in particular paragraphs 6.14 to 6.17
41 See in relation to pharmacists, for example, paragraph 8 of Schedule 1 of The National Health Service (Pharmaceutical Services) Regulations 2005 SI 2005/641. See paragraph 3 of Schedule 2 to those Regulations for dispensing doctors.
(1) Where a pharmacist is presented with, or receives from the ETP service, a prescription form or a repeatable prescription, the pharmacist shall only provide the drugs or appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 5(2) or (3); and

(b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985 and the following provisions of this Part.

...(12) Where a drug has an appropriate non-proprietary name and it is ordered on a prescription form or repeatable prescription either by that name or by its formula, a pharmacist may provide a drug which has the same specification notwithstanding that it is a Scheduled drug [a Scheduled drug being a drug or substance appearing in Schedule 1 or, subject to exceptions, Schedule 2 to The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 – see paragraph 4.2 above, provided that where a Scheduled drug is in a pack which consists of a drug in more than one strength, such provision does not involve the supply of part only of the pack.

(13) Where a drug which is ordered as specified in sub-paragraph (12) combines more than one drug, that sub-paragraph shall apply only if the combination has an appropriate non-proprietary name, whether the individual drugs which it combines do so or not.

4.9 This means that 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 (from paragraph 12 above) a branded drug which was not actually prescribed.

4.10 No similar control exists, however, in respect of the dispensing of drugs in hospitals. PCTs 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.
5 DRUG TARIFFS AND REIMBURSEMENT

5.1 The relevant Drug Tariff (for each constituent part of the UK) sets out the price at which, among other things, drugs supplied under the NHS will be reimbursed.

England and Wales

5.2 Section 42 of the National Health Service Act 1977 provides the Secretary of State with the power to make Regulations 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.

5.3 Regulation 56 of the National Health Service (Pharmaceutical Services) Regulations 2005\textsuperscript{42} is the current regulation made for the above purpose in England. Sub-paragraph (1)(d) is the particular provision under which the Drug Tariff sets reimbursement prices for drugs provided under the NHS:

\begin{quote}
56.— Standards of, and payments for, drugs and appliances

(1) For the purpose of enabling arrangements to be made for the provision of pharmaceutical services, the Secretary of State shall compile and publish a statement (in these Regulations referred to as “the Drug Tariff”) which he may amend from time to time and which, subject to paragraph (2), shall include—

(a) the list of appliances for the time being approved by the Secretary of State for the purposes of section 41 (arrangements for pharmaceutical services) of the Act and, in the case of a restricted availability appliance, the categories of persons for whom or purposes for which the appliance is approved;

(b) the list of chemical reagents for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

(c) the list of drugs for the time being approved by the Secretary of State for the purposes of section 41 of the Act;

(d) the prices on the basis of which the payment for drugs and appliances ordinarily supplied is to be calculated;

(e) the method of calculating the payment for drugs not mentioned in the Drug Tariff;

(f) the method of calculating the payment for containers and medicine measures;

(g) the dispensing or other fees or allowances payable in respect of the provision of pharmaceutical services or directed services;

(h) the dispensing or other fees or allowances payable in respect of the temporary provision of pharmaceutical services or directed services under regulation 54;
\end{quote}

\textsuperscript{42} ibid
(i) arrangements for claiming fees, allowances and other remuneration for the provision of pharmaceutical services or directed services; and

(j) the method by which a claim may be made for compensation for financial loss in respect of oxygen equipment specified in the Drug Tariff.

(1A) The Primary Care Trust shall make payments, calculated in the manner provided by the Drug Tariff or in accordance with any determination made by virtue of paragraph (2) (subject to any deduction required to be made by regulations made under section 77 of the Act) to chemists in respect of drugs and appliances, containers, medicines measures and dispensing fees and other fees and allowances.

(2) The Drug Tariff may state in respect of any specified fee or allowance falling within paragraph (1)(g) or (h), or any other specified fee, allowance or other remuneration in respect of the provision of pharmaceutical services or directed services by chemists included in the pharmaceutical list of a Primary Care Trust, that the determining authority for that fee, allowance or other remuneration for those chemists is the Primary Care Trust, and in such a case paragraphs (5) and (6) shall apply.

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

5.8 The Drug Tariff (notably the Part VIII basic prices) for England and Wales is amended monthly by administrators on behalf of the Secretary of State, pursuant to Regulation 56(1).

Scotland

5.9 Regulation 9 of the National Health Service (Pharmaceutical Services)(Scotland) Regulations 1995,46 made under section 27 of the National Health Service (Scotland) Act 1978, makes similar provision in respect of Scotland as does Regulation 56 for England and Wales, cited above. The Scottish Drug Tariff,46 like that for England and Wales, is amended monthly.

Northern Ireland

5.10 In respect of Northern Ireland, regulation 9 of the Pharmaceutical Services Regulations (Northern Ireland)47 provides for the creation and updating of the Drug Tariff. This is done by the Department of Health, Social Services and Public Safety.

45 SI 1995/414
46 This can be found at [http://www.isdscotland.org/isd/info3.jsp;jsessionid=9504C27713F192DE1AA662C45CFB838E?pContentID=2245&p_appli...]
47 SR 1997/381
EC LAW – PRICING AND REIMBURSEMENT

6.1 Pharmaceutical prices and pharmaceutical price regulation in national health systems are not harmonised at EU level. Rather, member states remain responsible for such matters at national level.

6.2 However, national systems operate within the framework of the so-called 'Transparency Directive.'\(^{48}\) They must also comply with other EC rules such as those on the free movement of goods, state aid and competition.


6.3 Whilst one of its preambles states that the Transparency Directive is a first step towards removing disparities between Member States which may hinder or distort intra-Community trade in medicinal products, its provisions do not remove Member States' sovereignty in setting mechanisms for regulating pharmaceutical prices. This is explicitly recognised in another preamble, which states that the directive is not to affect:

- the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products, or
- national policies on price setting and on the determination of social security schemes except as far as it is necessary to attain transparency with the meaning of the directive.

6.4 The same point is also implicitly recognised throughout the directive's substantive provisions.

6.5 The Transparency Directive does, however, impose a legal framework within which this national sovereignty may be exercised, reflecting what is said above – that Member States' powers, and the price regulation schemes they establish, are subject to EC law generally. So, the Directive lays down a series of requirements (some more detailed than others) intended to ensure that all concerned can verify that national measures do not amount to restrictions on the free movement of goods.\(^{49}\)

6.6 The directive's principal constraints on Member States' powers are its requirements for clarity and publicity in national pharmaceutical pricing arrangements and the criteria on which they are based. In particular, Member States are required to provide to the Commission specified information about those arrangements.


\(^{49}\) The final preamble makes clear this purpose, '…it is urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto'
6.7 Member States were required to implement measures to comply with the Transparency Directive by 31 December 1989 and to notify those measures to the European Commission 'forthwith' (Article 11(1)). However, the directive also contains ongoing obligations to communicate information to the Commission, for example where the national measures are changed.

6.8 The PPRS is a pharmaceutical price (profit) regulation measure the UK has adopted in pursuance of the Transparency Directive.

The Transparency Directive's detailed requirements

6.9 **Article 1** requires that

> 'member states shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this Directive.'

6.10 Articles 2 and 3 apply where:

- the marketing of a medicinal product is permitted only after the competent authorities’ approval of the price (Article 2), and
- an increase in the price of a medicinal product is permitted only after the competent authorities’ prior approval (Article 3).

6.11 They require Member States to ensure that competent authorities’ decisions on medicinal product prices are communicated to applicant medicinal product marketers within specified time frames – generally 90 days. Failure to act within the time frame should allow the applicant to proceed as if approval is granted. These articles also require competent authorities to:

- give applicants a statement of reasons based on objective and verifiable criteria wherever applications for price approval are rejected, and
- inform applicants of the remedies available following any rejection and the time limits for applying for them.

6.12 Further, they require Member States at least once a year to publish information about medicinal products whose prices have been fixed or increased during the relevant period. Publication must be in an appropriate publication and the information communicated to the Commission.

6.13 **Article 4** applies where Member States' competent authorities have imposed a price freeze on all medicinal products or certain categories of them. Member States must ensure a medicinal product marketer can apply for a derogation from any price freeze and receive a reasoned decision within 90 days. Member States must also review price freezes at least once a year to determine whether they should continue.
6.14 **Article 5** comes into play where a Member State regulates pharmaceutical prices by a scheme of direct or indirect profit controls. The Member State must publish the following in an appropriate publication and communicate it to the Commission:

- the method or methods used to define profitability: return on sales and/or return on capital
- the range of target profit currently permitted
- the criteria according to which target rates of profit are set and the criteria according to which profits above that target may be retained, and
- the maximum percentage profit above the target rate that may be retained.

6.15 They must update this information at least once a year or when significant changes are made.

6.16 Article 5 also deals with the situation where a Member State operates a price control system for some pharmaceuticals and a profit control system for others. It says Articles 2 – 4 may apply to the price control system.

6.17 **Article 6** applies where a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include it in a 'positive list' of products so covered. Decisions on applications for inclusion on the list must generally be made and communicated to applicants within 90 days (or 180 where the price also needs to be approved). Applicants must be given statements of reasons based on objective and verifiable criteria wherever decisions are made that medicinal products should not be on the list, together in most cases with details of available remedies. Some decisions must also be published. Member States are also required to publish and communicate to the Commission their criteria for including products on the list and, on an annual basis, the products covered by their health systems and the prices fixed.

6.18 Article 7 applies where Member States’ competent authorities can exclude individual or categories of medicinal products from national health systems ('negative lists'). Similar rules as to decisions to exclude products, their communication and publication and the publication and communication of the criteria for exclusion apply under Article 7 as under 6.

6.19 Part XVIII C of the Drug Tariff for England and Wales\(^\text{50}\) contains criteria notified to the European Commission under Article 7 of this Directive.

6.20 **Article 8** requires Member States to communicate to the Commission any criteria:

- for the therapeutic classification of medicinal products in the national social security system, and

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\(^{50}\) The following is a link to the entry page for the electronic drug tariff  
http://www.ppa.org.uk/ppa/edt_intro.htm
• used to verify the fairness and transparency of the prices charged for transfers within a group of companies of the ingredients of medicinal products.

6.21 Article 9 provides that the European Commission was by 31 December 1991 to have made to the Council a proposal for appropriate measures leading towards the abolition of any remaining barriers to, or distortions of, the free movement of medicinal products, to bring the sector closer into line within the normal internal market conditions. The Council was to decide on the proposal within one year. However, this did not lead to further price-harmonising legislation.

6.22 Article 10 provided for the setting up of a, 'Consultative Committee for the implementation of Directive 89/105/EEC', to be attached to the Commission. Its task is to examine questions relating to the application of the Transparency Directive.

6.23 Article 11 contains the Member States' obligations to communicate to the Commission the text of their implementing measures (on medicinal product pricing, profitability of medicinal product manufacturers and the coverage of medicinal products by national health insurance systems) as referred to above. Amendments and modifications of implementing measures must be communicated to the Commission 'forthwith'.

Litigation under the Transparency Directive

6.24 The following are cases brought in the UK or decided at a European level in respect of the Directive.

Case C-229/00 Commission v Finland

6.25 The Commission successfully challenged Finland's implementation of the first two paragraphs of Article 6 of the Directive in that its procedures failed to give reasons to applicants where the authorities, by refusing to include in a list of active ingredients qualifying for higher-rate cover under the national social security system, effectively decided on the exclusion from that list of medicinal products not containing those ingredients.

EFTA E-2/98 Federation of Icelandic Trade v Iceland

6.26 This case concerned the relationship between Articles 3 and 4 of the Directive, in respect of price decisions and whether or not Article 4 on general measures took priority over Article 3. The Court advised that Article 4 took priority and also that in the context of that provision, 'price freeze' should be interpreted to include a general decrease in wholesale prices.

ECJ C-245/03 Merck, Sharp & Dohme BV v Belgium

6.27 The two issues referred by the national court were i) whether or not the time limit under Article 6 of the Directive for making a decision on an application is mandatory and ii) what was the consequence of exceeding the time limit in the sense of the
response to be given to the application made under that Article. The Court concluded on i) that the time limit is mandatory and on ii) that, in the absence of express language in the Directive, failure to comply with the Article 6 time limit did not mean that the application should automatically succeed.

**ECJ C-296/03 Glaxosmithkline SA v Belgium**

6.28 In a similar vein to Case C-245/03, this also considered the time limit imposed by Article 6 of the Directive. Again, the Court stated that the time limit was mandatory. The further question was whether or not the fact that the time limit laid down in the first sub-paragraph of Article 6(1) was exceeded precludes the competent authorities from formally adopting a new decision when the previous decision had been annulled in court proceedings. The Court held that the answer to this question was for the Member States to determine.

**ECJ C-424/99 Commission v Austria**

6.29 This case concerned a challenge by the Commission to Austria’s implementation of Article 6 of the Directive. The challenge was based on three grounds: i) that the time limit in Article 6(1) had not been observed; ii) the statement of reasons for refusal of a request for inclusion on a list was either non-existent or wrong, contrary to Article 6(2); and iii) contrary to Article 6(2), no remedies were provided in the event of refusal of a request.

6.30 For technical reasons, the only part of the challenge which the Court considered was iii) and, on the facts, it found Austria to be in breach. In assessing the matter, the Court rejected an argument by Austria that Article 6 was inapplicable because the register in question was not a ‘positive list’ under Article 6.

**UK (R (on the application of Pfizer Ltd.)) v. Secretary of State for Health [2003] 1CMLR 19**

6.31 The Court of Appeal was asked to consider the decision of the Secretary of State that Viagra was not to be reimbursed under the National Health Service. It was, in essence, a challenge to the political decision of the Secretary of State not to prioritise Viagra and the condition for which it is marketed under the NHS. The basis of the challenge was the application of the following criterion, notified to the Commission under Article 7(2) of the Directive:

‘...a medicinal product or a category of medicinal products may be excluded entirely from supply on NHS prescription. It may alternatively be excluded except in specified circumstances, or except in relation to specified conditions or categories of condition, or specified categories of patient. A medicinal product or a category of them may be so excluded where the forecast aggregate cost to the NHS of allowing the product (or category of products) to be supplied on NHS prescription, or to be supplied more widely than the permitted exceptions, could not be justified having regard to all the relevant circumstances including in
particular: the Secretary of State’s duties pursuant to the NHS Act 1977 and the priorities for expenditure of NHS resources.’

6.32 It was alleged that the decision to restrict the use of Viagra, on the basis as found by the Court of Appeal not of clinical or cost-effectiveness but rather on the Secretary of State’s assessing the need it addressed as having a lower priority than other calls on NHS funds,51 failed to contain a statement of reasons, ‘based on objective and verifiable criteria’ as required by Article 7. In submissions, the challenge was expressed to be, ‘not merely to the adequacy of the Minister’s reasoning but rather to his having conducted no analysis and provided no reasoning at all.’52

6.33 Lord Justice Simon Brown held the following:53

‘17. Of course the time may come when, perhaps pursuant to the Health Committee’s recommendation (ff) quoted above, the Government formulates ‘an explicit set of ethical and rational values’ so as ‘to allow the relative costs and benefits of different areas of NHS spending to be comparatively assessed in an informed way’. As the Government’s response indicates, however, that could only be achieved in the long term. Meantime it seems to me inescapable that affordability, in the sense of choosing between competing priorities as to where funds should be allocated, must be regarded as a political decision to be taken by Government. Untill ‘an explicit set of ethical and rational values’ is established, any ranking of NHS priorities otherwise than on a political basis would indeed be ‘artificial’ as the respondent’s final letter of March 27, 2002 suggested.’

‘18. With these thoughts in mind I return to the central question arising on this appeal: does Art.7 require the Secretary of State, before he can restrict the prescription on the NHS of any product, to conduct the sort of analysis of competing priorities which the Health Committee contemplates may one day become possible? In my judgment the answer to this question is plainly not. Nor do I think that it requires any other form of analysis and explanation.’

6.34 Lord Justice Brown agreed with Lord Justice Simon Brown and expressed some additional opinions. He suggested54 that the transparency and non-discriminatory objective and requirement, as stated by the ECJ in Duphar55 was carried over into the Directive. Following from that statement, he added:

‘For the criteria to be ‘verifiable’, all that is necessary is that they should be published and available, in particular to would-be importers, to satisfy themselves that they do not contain disguised restrictions on intra-Community trade. And the measures are ‘objective’, in the sense used by the Court in Duphar, if they are

51 From the judgment of Lord Justice Simon Brown at page 647, paragraph 9
52 Ibid
53 Ibid at page 650
54 Ibid at page 652, paragraph 26
55 Case C-238/82
based on a legitimate aim, that of improving the economics of the state health system.'

Other EC law

6.35 As noted above, although pharmaceutical price regulation is an area in which Member States retain sovereignty, in exercising that sovereignty they are generally subject to EC law, in particular the rules governing the free movement of goods, state aid and competition. National pharmaceutical price regulation measures must comply with those rules.

Free movement of goods

6.36 Article 28 EC Treaty\textsuperscript{56} (formerly Article 30) says:

'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.'

6.37 Such restrictions and measures may, however, be justified if they fall within Article 30 EC Treaty (formerly Article 36), which says, so far as relevant:

'The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of .... public policy ......; [and] the protection of health and life of humans ...... Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'

6.38 In the following cases, Member States' pharmaceutical price regulation measures were held to breach Article 28 (with no justification under Article 30).

Roussel Laboratorias BV v État Néerlandais\textsuperscript{57}

6.39 The Netherlands introduced measures under which the price of imported medicines was tied to the manufacturer’s usual basic price for products intended for consumption in its home state. The price of domestic medicines was based on a price freeze at a fixed date.

6.40 The European Court of Justice ('ECJ') said:

- any measures which are capable of hindering, directly or indirectly, actually or potentially, trade between Member States are to be regarded as measures having an effect equivalent to quantitative restrictions

- systems regulating prices applicable to domestic products and imported products alike do not in themselves constitute measures having an effect equivalent to

\textsuperscript{56} Treaty Establishing the European Community
\textsuperscript{57} Case 181/83, [1983] ECR 3849
quantitative restrictions but may have such an effect when the prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than that of domestic products.

- article 30 [now article 28] precludes a Member State from introducing in respect of pharmaceutical products imported from other Member States legislation which refers to the manufacturer’s basic prices usually charged for products intended for consumption within the territory of the Member State in which they are produced, where the legislation applicable to domestic production is based solely on a freeze of the level of prices at a given reference date, and
- a situation of that kind can have the effect of placing the sale of imported products at a disadvantage by rendering such sale more difficult, impossible or, in any event, less profitable than the sale of domestic products whenever the level of prices applying to imported products is lower than that applicable to domestic products.

**Commission v Italy**

6.41 Italy adopted a method of fixing prices for pharmaceutical products which expressly provided that:

- the development of the national industry and research on the national territory should be promoted
- the cost components related thereto may be taken into account to a greater extent than the corresponding cost components for imported products, and
- under which the supplementary costs and charges inherent in importation were not mentioned among the factors to be taken into consideration in the fixing of prices of imported products. The ECJ held that this constituted a measure having an effect equivalent to quantitative restrictions on imports within the meaning of Article 30.

**Commission v Belgium**

6.42 In Belgium pharmaceutical prices were very tightly regulated, with maximum prices set at a low level that could only be increased under very strict conditions. As a result, profit margins were low and it was difficult for pharmaceutical companies to invest in Belgium in employment and R&D. The Belgian authorities' response was to pass a law under which the state and pharmaceutical companies could enter into 'programme contracts'. Under these, pharmaceutical companies were allowed to increase the price of their products in return for undertaking to promote laboratory research, investment and employment in Belgium and Belgian exports. The conditions attached meant, in

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58 Case 56/87, [1988] ECR 2919
practice, only pharmaceutical products developed and manufactured in Belgium could be covered by the contracts.

6.43 The ECJ said:

'The introduction by a Member State in the pharmaceutical products sector of a system of programme contracts from which only national undertakings can benefit, and which, in return for the commitments on investment, research, employment and exports, allows derogations to be granted from the general rules on price control and places the products that benefit from the system at an advantage as regards approval for re-imbursement, constitutes an infringement of Article 30 of the Treaty. That system is such as to place imported products at a disadvantage and, therefore, constitutes a measure having equivalent effect to a quantitative restriction prohibited by that provision.'

The Queen v The Secretary of State for Health ex parte Association of Pharmaceutical Importers, Association of the British Pharmaceutical Industry

6.44 In this case, the applicants (BAEPD and Dowelhurst Limited) challenged the modulation provisions of the 1999 PPRS on the basis that they were contrary to EC law, namely Articles 28 EC Treaty (quantitative restrictions on imports and all measures having equivalent effect) and 81 (agreements or decisions of undertakings and concerted practices which have as their object or effect the restriction or distortion of competition). The applicants claimed that, by allowing price cuts to be modulated, scheme members could target price cuts against parallel imports, thus restricting imports and / or distorting competition.

6.45 The judge at first instance seemed to focus on the maintenance of free market competition under the modulation provisions, in the sense that price cuts could be targeted as the scheme members chose, in the ordinary way.

6.46 The decision that the modulation provisions were not, on the evidence available to the court, unlawful was appealed to the Court of Appeal. That court sidestepped a detailed analysis of the modulation provisions by reason of the following conclusion:

'28. We have no doubt that the modulation provisions in chapter 21 of the 1999 scheme must be considered as part of the whole scheme. They were an essential element of the whole scheme and are in part at least the result of the Department’s requirement that there should be a price cut of 4.5 per cent...

32. As we have said the case as pleaded and argued was that only the modulation provisions in chapter 21 were illegal. For the reasons we have given,

60 The Queen v The Secretary of State for Health ex parte British Association of European Pharmaceutical Distributors and Dowelhurst Limited v Association of the British Pharmaceutical Industry [2001] EWHC Admin 183
that case is based upon a misapprehension as to the nature of the 1999 scheme. Its legality can only be and has to be considered as a whole. That was not the basis of the appellants’ case. It follows that the relief claimed cannot be granted and the appeal must fail.’

6.47 The judge at first instance reached the same conclusion, but nonetheless analysed the modulation provisions, in conjunction with the price cut.

Article 28

6.48 The judge concluded that the modulation provisions were not contrary to Article 28, principally because they were non-discriminatory. Measures taken under those provisions could have also been taken under ordinary market competition. The judge nonetheless went on to consider whether or not, had the modulation provisions fallen within Article 28 TEC, they would have constituted a ‘selling arrangement’ within the meaning of the Keck\(^1\) judgment (selling arrangements which applied to all relevant traders and which affected in the same manner the marketing of domestic products and those imported from other Member States). The judge expressed the view that the provisions did constitute such a selling arrangement and that ‘all relevant traders’ means those who supply branded pharmaceutical products to the NHS, to all of whom the PPRS was open.

6.49 The judge did not go on to consider whether or not, had the provisions been contrary to Article 28, they could be justified under Article 30 TEC.

6.50 When it came to consider the case, the Court of Appeal, though not analysing the application of Article 28, quoted the conclusions of the judge at first instance on the compatibility of an overall 4.5 per cent price cut with Article 28 and made the following observation:

‘38. That conclusion disregards the way that drugs in the UK are supplied and priced. Drugs are supplied according to the needs of the patient at a price which is set in the Drug Tariff. In the case of patented drugs, the price is the list price of the manufacturer. It follows that if there was no restriction upon prices except a requirement to price cut, a company could reduce its prices on a product to meet competition from a parallel import of that product. But it could do that knowing that its overall profitability would not be reduced because it could recoup any loss from the price paid for other branded drugs prescribed by doctors...’

Article 81

6.51 The judge at first instance concluded that the PPRS constituted an agreement between undertakings. On the evidence before him (namely a statement made by a party to the PPRS negotiations) and for the reasons given in relation to Article 28, the judge

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\(^1\) ECJ joined cases C-267-268/91
concluded that the object of the agreement / modulation provisions was not to restrict or distort competition but rather to control the profits of the pharmaceutical manufacturers. The finding as to the effect of ordinary market competition also led the judge to conclude that the modulation provisions had no anti-competitive effect either.

6.52 As identified above, the Court of Appeal refrained from opining on the lawfulness or otherwise of the modulation provisions or the PPRS as the former was indivisible from the scheme as a whole and the case presented was insufficient to properly examine the latter.
7.1 Under Article 87(1) EC Treaty (formerly Article 92(1)):

'Save as otherwise provided in this Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the common market.'

7.2 Such state aids are consequently unlawful unless they fall within a derogation in Articles 87(2) or 87(3).

7.3 In simple terms, there are four basic elements to the test for state aid:

- aid granted by a Member State – there must be a loss or potential loss of State resources. A regulatory provision with no state resources involved would not constitute a transfer in this sense\(^{62}\)
- advantage to a particular undertaking or a class of goods – the aid must confer an advantage on the recipient(s), for example a loan on better than commercial terms or higher than market price paid for goods. In addition, in order to confer an advantage, the transfer must be selective for example tax credit made available to undertakings in a particular sector\(^{63}\) or geographical location
- distorts or threatens to distort competition – in practice, this test appears to have a low threshold and is satisfied in most if not all cases where the first two criteria are met
- affect on trade between Member States – again, in practice this test appears to have a low threshold although it is not always satisfied (for example in respect of local visitor attractions which are not regarded as destinations by visitors from afar).

7.4 The following derogation in Article 87(3) may be relevant in the context of the PPRS:

'Article 87(3)(c) - aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest'

7.5 From 1 January 2007, the European Commission’s new Community Framework for State Aid for research and development and innovation\(^{64}\) will come into effect. Part of its purpose is to provide,

'for the assessment of measures falling within its scope, not only rules on the compatibility of certain aid measure (Chapter 5) but also, due to the increased risk

\(^{62}\) See for example ECJ Case C-379/98 PreussenElektra AG v. Schleswag AG
\(^{63}\) See for example ECJ Case C-143/99 Adria-Wien Pipeline GmbH
of certain aid measures to distort competition and trade, additional elements concerning the analysis of the incentive effect and necessity of aid (Chapter 6) and an additional methodology to be applied in case of detailed assessment (Chapter 7)\textsuperscript{65}.

7.6 In the Belgian case\textsuperscript{66} above the European Commission took action against the system of programme contracts as amounting to unlawful state aids within Article 87(1). In its Decision it said:\textsuperscript{67}

'The price increases authorized within the framework of the conclusion of programme contracts constitute State aid within the meaning of Article [87] (1), since they enable the beneficiaries to carry out investment and/or research, to take on staff and to promote exports without having to bear the normal costs of such measures.'

7.7 It also said,

'In addition, the aid does not fulfil the conditions laid down in order to qualify for one of the exemptions provided for in Article [87](2) and (3).'

7.8 More information on the state aid rules can be found on the DTI website.\textsuperscript{68}

\textsuperscript{65} See Chapter 1.2  
\textsuperscript{66} See also paragraph 6.42 above. C-249/88 in which the Commission took action against Belgium in respect of the programme contracts alleging that they infringed Article 30 EC (now Article 28)  
\textsuperscript{67} Commission Decision 92/327/EEC, OJ 1992 L182/89  
\textsuperscript{68} http://www.dti.gov.uk/bbf/state-aid/index.html
COMPETITION LAW

8.1 Articles 81 and 82 EC Treaty (mirrored in the UK, where the effect on competition is within the UK as opposed to the European Community, by the restrictions in sections 2 and 18, respectively, of the Competition Act 1998), prohibit:

Article 81 – '...all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market...'

Article 82 – '...any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it...in so far as it may affect trade between Member States.'

ECJ Case C-53/03 Syfait and others v. Glaxosmithkline AEVE

8.2 This case concerned a reference from the Greek competition commission concerning an allegation that in refusing to meet in full orders for its products placed with it by Greek wholesalers, Glaxosmithkline AEve abused its dominant position in the relevant market contrary to Article 82 EC. The ECJ rejected the reference from the national arbiter on the ground that it was not a court or tribunal within the meaning of Article 234. Nonetheless, Advocate General Jacobs, having taken a different view on that point, expressed the following.

8.3 In line with case law of the ECJ (for example Cases C-6/73 Commercial Solvents and C-27/76 United Brands), a refusal by a dominant undertaking to supply orders placed with it does not necessarily constitute an abuse of that position. An analysis of the factual and economic context is required in order to determine, in each case, whether or not there has been an abuse and whether or not such action can be justified.

8.4 AG Jacobs concluded as follows:

'100. In the light of all of the factors considered above, I consider that a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade is capable of justification as a reasonable and proportionate measure in defence of that undertaking's commercial interests...Given the specific economic characteristics of the pharmaceutical industry, a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate. Moreover, it cannot be assumed that parallel trade would in fact benefit either the ultimate consumers of pharmaceutical products or the Member States, as primary purchasers of such products.

101. However, I regard the conclusion which I have reached here as highly specific to the pharmaceutical industry in its current condition and to the particular type of conduct at issue in the present proceedings.'
102. I think it is highly unlikely that any other sector would exhibit the characteristics which have led me to conclude that a restriction of supply in order to limit parallel trade is defensible in relation to pharmaceutical products. Equally, if the economic and regulatory context of the pharmaceutical sector in Europe were to change, it might then be necessary to reconsider the reasonableness and proportionality of restricting supply in a low-price Member State.

103. I also consider that conduct by a dominant pharmaceutical undertaking which more clearly and directly partitioned the common market would not be open to a similar line of defence. The proportionality of the restriction of supply derives in part from the very limited contribution which it makes, in the pharmaceutical sector, to market partitioning.

104. Lastly, I would note that the above analysis does not preclude the possibility that a restriction of supply by a dominant pharmaceutical undertaking might fall foul of the Court’s established case-law on refusal to supply if it had negative consequences for competition arising other than as a consequence of its restriction of parallel trade.‘

8.5 The Attorney General summarised as follows69 four specific factors in particular in the pharmaceutical sector which led to him to the above conclusions:

- the pervasive and diverse State intervention in the pricing of pharmaceutical products, which is responsible for price differentials between the Member States
- the regulation by the Community and the Member States of the distribution of pharmaceutical products, which establishes nationally demarcated obligations upon pharmaceutical undertakings and wholesalers to ensure the availability of adequate stocks of those products
- the potentially negative consequences of parallel trade for competition, the common market, and incentives to innovate, given the economic characteristics of the pharmaceutical industry
- the fact that end consumers of pharmaceutical products may not in all cases benefit from parallel trade and that public authorities in the Member States, as the main purchasers of such products, cannot be assumed to benefit from lower prices, given that they are themselves responsible for fixing prices within their territories.

CFI Case T-168/01 GlaxoSmithKline Services Unlimited v Commission

8.6 This case was a challenge by GlaxoSmithKline Services Unlimited (‘GSK’) to Commission Decision 2001/791/EC in which the Commission expressed its first two findings that:

69 Case C-53/03 at paragraph 105
Article 1 - Glaxo...has infringed Article 81(1) of the Treaty by entering into an agreement with Spanish wholesalers operating a distinction between prices charged to wholesalers in the case of domestic resale of reimbursable drugs to pharmacies or hospitals and higher prices charged in the case of exports to any other Member State.

Article 2 - The request by Glaxo...for an exemption of the agreement referred to in Article 1, pursuant to Article 81(3) of the Treaty, is rejected.

8.7 The facts can be summarised as follows.

Spanish regulatory framework

8.8 Spanish authorities had instituted a law\(^70\) (modified over time) which provided that the maximum price to be charged by pharmaceutical companies to wholesalers for each pharmaceutical product, provided it was to be both dispensed in Spain and financed by the social security system or by state funds related to health was to be set by the Ministry of Health and Consumers. That law also provided that the Ministry sets the margins of wholesalers and pharmacies, thereby effectively also setting the maximum retail price. Prices of products not financed by the social security system could be set by the pharmaceutical companies but must be based on objective and verifiable criteria.

GSK agreements

8.9 GSK (Glaxo Wellcome SA as it then was) notified to the Commission in March 1998 new sales conditions and thereafter provided it with supplementary information. By the notification, it sought a decision from the Commission declaring that the conditions were not contrary to Article 81(1) EC or, alternatively, that as an agreement contributing to promoting technical progress, they should be exempted under Article 81(3) EC. Those sales conditions were said by GSK to apply to a total of 82 pharmaceutical products, all of which were prescription drugs. Clause 4 established a dual pricing regime for the products in question:

'A. Pursuant to the provisions of subsections 1 (first paragraph) and 2 of Article 100 of Law 25/1990 of 20 December 1990 concerning medicine, the price of pharmaceutical products of GW SA and its subsidiary companies shall, in no event, exceed the maximum industrial price, established by the Spanish health authorities when the two factors which allow for the application of the said legal rules are present, namely:

- that the aforementioned pharmaceutical products are financed by the funds of the Spanish social security or by Spanish public funds,
- that the acquired pharmaceutical products are subsequently marketed at a national level, that is, through pharmacies of Spanish hospitals.'

\(^70\) Article 100 of Law 25/1990 (Ley del Medicamento)
B. In the absence of one of those two factors (i.e. in all cases where Spanish law gives full freedom to the laboratories to set the prices of their pharmaceutical products themselves), GW SA and its subsidiaries will fix the price of their pharmaceutical products according to real, objective and non-discriminatory economic criteria and completely irrespective of the destination of the product determined by the purchasing warehouse.

8.10 Thus Spanish wholesalers were offered one, effectively lower, price if the products were to be sold for use on the Spanish market and another, higher price, if they were to be exported.

8.11 Contrary to the submission of GSK, the Commission concluded that the sales conditions constituted agreements, within the meaning of Article 81 EC Treaty.

8.12 GSK in its application acknowledged that the conditions could affect trade between Member States (in particular affecting the parallel trade of affected products from Spain to the UK). It stated, however, that the objective of Clause 4 was among other things to, 'allow consumers in Spain to obtain GW products without prejudicing the ability of GW to fund research and development in the Community…'

**Commission Decision 2001/791/EC**

8.13 The Commission concluded that:

'GW’s objective is clearly to impede parallel trade by obliging Spanish wholesalers to purchase the drugs at prices which are higher than the maximum industrial price for domestic sales.'

8.14 The Commission went on, at recital 124 of its Decision, to state that:

'The Court of Justice (and Court of First Instance) have always qualified agreements containing export bans, dual-pricing systems or other limitations of parallel trade as restricting competition 'by object'. That is to say, prohibited by Article 81(1) without there being any need for an assessment of their actual effects. In principle, they are not eligible for exemption pursuant to Article 81(3).

8.15 GW had contested that analogy to dual pricing on the basis that the national authorities set one of the price levels – the Commission rejected this argument by reasoning that it, 'overlooks the fact that pharmaceutical companies have negotiating power when discussing prices for domestic sales.'

8.16 In recitals 126 to 146, the Commission also analysed whether Clause 4 had an anticompetitive effect: it concluded that it did.

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71 Recital 116. See also recital 125
72 Recital 120
In considering the application of Article 81(3) to the sales conditions, the Commission reached the following conclusions on the relevant criteria:

- **technical progress** – the Commission decided that GSK had failed to prove that there was a causal link between parallel trade and investments for research and development. The Commission also decided that, in any event, GSK had ‘overstated the magnitude of any impact that parallel trade might have on such investments’.

- **improving distribution** – the Commission failed to accept any of the arguments of GSK that parallel trade caused delays for product launches in Spain, that it disrupts GSK’s distribution system or that it prevents GSK from planning its distribution rationally.

- **benefit to consumers** – the Commission stated that, ‘since GW has not demonstrated that the restriction of parallel trade actually achieves any of the benefits required under the first condition [the previous two bullet points], the second condition of Article 81(3) can also not be fulfilled and therefore needs no further examination.’ Nonetheless, the Commission did undertake a limited examination of a number of GSK’s arguments on this point but found none of them to be convincing.

- **indispensability** – the Commission concluded that, ‘since there is not evidence that...[the new sales conditions] achieve the objectives of promotion of technical progress and improvement of distribution, it follows that there is no contribution whose indispensability to the attainment of these objectives could be analysed.’

**Court of First Instance**

GSK challenged the Commission Decision on a number of grounds, some related to the finding of an infringement of Article 81(1) EC, others to the rejection by the Commission of GSK’s claim for exemption under Article 81(3) EC. Only a selection of those bases are examined below, others being of a nature less relevant to the PPRS market study.

At paragraph 103 of its judgment, the CFI set out the following:

‘GSK does not dispute the material accuracy of the facts on which the Commission relied for the purpose of applying Article 81(1) EC, but contests the Commission’s assessment of those facts. All of the applicant’s criticisms relate, in substance, to the consequences to be drawn, when analysing the existence of a restriction of competition, from the legal and economic context peculiar to the medicines sector (see page 40 of this Annex on ECJ Case C-53/03). More particularly, its criticisms concern, in the first place, the competitive situation...’

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73 Recital 154
74 Recital 187
existing before Clause 4 of the General Sales Conditions was adopted and, in the second place, the restriction of competition attributed to that clause.'

8.20 The CFI recognised\textsuperscript{75} that laws of a number of Member States ‘go beyond the mere regulation of an economic activity, in particular in matters of prices (Case 181/82 Roussel and Others [1983] ECR 3849, paragraph 8). The coexistence of those different national regulations may distort competition (Joined Cases C-267/95 and C-268/95 Merck and Beecham [1996] ECR I-6285, paragraph 47). It tends, moreover, to favour a certain partitioning of the national markets on that point...’

8.21 The Court went on to explain that as competition was not precluded in the medicines sector by such regulation (for example, competition remains particularly in respect of innovation), Article 81(1) EC was not rendered inapplicable, even though competition may be restricted by that same regulation.\textsuperscript{76}

**Anti-competitive object and legal and economic context**

8.22 The CFI noted at paragraphs 114-116 of its judgment that agreements which seek to prohibit or treat unfavourably parallel trade must in principle be regarded as having as their object the restriction of competition. It went on to say\textsuperscript{77}, however, that:

‘...GSK is correct to maintain that, having regard to the legal and economic context, the Commission could not rely on the mere fact that Clause 4 of the General Sales Conditions established a system of differentiated price intended to limit parallel trade as the basis for its conclusion that that provision had as its object the restriction of competition.’

8.23 The CFI also noted\textsuperscript{78} that:

‘...while it is accepted that an agreement intended to limit parallel trade must in principle be considered to have as its object the restriction of competition, that applies in so far as the agreement may be presumed to deprive final consumers of...[the advantages of competition].

However, if account is taken of the legal and economic context in which GSK’s General Sales Conditions are applied, it cannot be presumed that those conditions deprive the final consumers of medicines of such advantages.’

8.24 At paragraphs 124 to 131 of its judgment, the CFI sets out the main characteristics of the legal and economic context, as stated to have been agreed by GSK:

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\textsuperscript{75} Paragraph 104 full ref. to CFI judgment  
\textsuperscript{76} Paragraph 108  
\textsuperscript{77} Paragraph 117  
\textsuperscript{78} Paragraphs 121 and 122
First, according to recitals 31, 36 and 50 to the Decision, the price of medicines reimbursed by the national health insurance schemes is not determined as a result of a competitive process throughout the Community but is directly fixed following an administrative procedure in most Member States and indirectly controlled by the other Member States.

Second, according to recital 31 to the Decision, at this stage the harmonisation of the applicable national provisions is limited. In fact, Directive 89/105 endeavours to provide that where the pricing of those medicines is provided for in national law it must be preceded by a transparent procedure and be based on objective and verifiable criteria. For the remainder, according to recital 50 to the Decision, national law may provide that various criteria are to be taken into account, depending on the policy pursued by the Member State concerned as regards public health and the financing of the national sickness insurance scheme, as Directive 89/105 also explains. That is the case, in particular, of Spanish law, which, according to recitals 37 and 38 to the Decision, provides for the direct fixing of a maximum wholesale price and the indirect fixing of a maximum retail price. United Kingdom law does not provide for the fixing of prices but, according to recitals 44 to 46 to the Decision, for control of pharmaceutical companies’ profits.

Third, according to recitals 29 to 31 and 34 to the Decision, the differences between the applicable national provisions are a structural cause of the existence of significant price differentials between Member States.

Fourth, according to recitals 30, 32 and 53 to the Decision, fluctuations in exchange rates are a cyclical cause of those price differentials. That phenomenon, which potentially affected all Member States of the Community on 6 March 1998, the date on which GSK notified the General Sales Conditions to the Commission, still affected the United Kingdom, Denmark and Sweden on 8 May 2001, the date on which the Commission adopted the Decision, as stated at recital 53 to the Decision.

Fifth, those price differentials are themselves the cause of parallel trade in medicines in the Community, according to recital 29 to the Decision. As indicated at recitals 33 and 34 to the Decision, the main Member States of destination of that parallel trade are Denmark, the Netherlands and the United Kingdom.

Sixth, certain Member States have adopted provisions which, independently of the question whether they are intended to encourage parallel trade – which the Commission explains at recitals 31, 33, 34, 36 and 52 to the Decision, but which GSK disputes –, may have such an effect. That is notably the case in the United Kingdom, where, as stated at recital 49 to the Decision, the National Health Service automatically pays pharmacists a sum equal to the manufacturer’s list price on the United Kingdom market, minus a standard discount of 4 to 5 per cent, which is supposed to correspond to the savings made by pharmacists where they obtain their supplies elsewhere, at a lower price.
131 Seventh, as stated at recitals 31 and 51 to the Decision, the patient generally bears only a limited part, although this varies from Member State to Member State, of the price of the medicines reimbursed by the national sickness insurance scheme which he consumes. The national sickness insurance scheme bears the essential part. That is notably the case in the United Kingdom, where, according to recital 48 to the Decision, the patient pays GBP 6 per item, unless he belongs to a category exempt from such payment.'

8.25 In criticism of the Commission’s analysis, however, the CFI continued at paragraph 133:

'At no point, however, does the Commission examine the specific and essential characteristic of the sector, which relates to the fact that the prices of the products in question, which are subject to control by the Member States, which fix them directly or indirectly at what they deem to be the appropriate level, are determined at structurally different levels in the Community and, unlike the prices of other consumer goods to which the Commission referred in its written submissions and at the hearing, such as sports items or motor cycles, are in any event to a significant extent shielded from the free play of supply and demand.

That circumstance means that it cannot be presumed that parallel trade has an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance scheme and thus confers on them an appreciable advantage analogous to that which it would confer if those prices were determined by the play of supply and demand.

Accordingly, it cannot be considered that examination of Clause 4 of the General Sales Conditions, which according to GSK is designed to ensure that the wholesale price set by the Kingdom of Spain is actually charged only for the medicines to which it was intended by law to apply, reveals in itself that competition is prevented, restricted or distorted.'

8.26 The CFI summed up its view of the Commission’s reasoning as to the anti-competitive object of Clause 4:

'147 Consequently, the principal conclusion reached by the Commission, namely that Clause 4 of the General Sales Conditions must be considered to be prohibited by Article 81(1) EC in so far it has as its object the restriction of parallel trade, cannot be upheld. As the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers. An analysis of the terms of Clause 4 of the General Sales Conditions, carried out in that context, therefore does not permit the presumption that that provision, which seeks to limit parallel trade, thus tends to diminish the welfare of final consumers. In this largely unprecedented situation, it cannot be inferred merely from a reading of the terms of that agreement, in its context, that the agreement is restrictive of competition, and it is therefore
necessary to consider the effects of the agreement, if only to ascertain what the regulatory authority was able to apprehend on the basis of such a reading.’

**Anti-competitive effect**

8.27 GSK accepted that Clause 4 had, or may have had, the effect of limiting parallel trade but denied that it had or may have had the effect of restricting competition. The CFI accepted that the former effect does not necessarily result in the latter and added that ‘[i]t is the repercussions which that restriction of parallel trade has or may have on one or other of the parameters of competition, such as the quantity in which a product is supplied or the price at which it is sold, that provides evidence of such a restriction [see Case C-28/77 Tepea v Commission, paragraphs 41, 43 and 56].’

8.28 Thus, said the CFI, after referring to the effect which Clause 4 had on parallel trade, the Commission was required to demonstrate an effect on competition. At paragraph 171, the Court explained that, while it was not in dispute that Clause 4 had the effect of restricting the freedom of Spanish wholesalers to choose their customers, it was still necessary to demonstrate that this restricted competition, to the detriment of the final consumer.

8.29 As to the existence of different prices in different Member States, the CFI determined, by reference to the different prices existing in separate geographic markets characterized by insufficiently homogenous conditions of competition, that in the legal and economic context of the relevant markets the existence of different prices was insufficient to support a conclusion that discrimination existed between equivalent transactions. The Court commented that, '[i]t is possible that GSK applies different prices because different markets exist and not so that different markets will exist.'

8.30 The CFI went on to add:

‘180. Such an explanation is suggested by the Commission itself, moreover, which indicated in Communication COM(1998) 588 final, paragraph 135 above, that the pharmaceutical companies apply price discrimination to reflect the differences in the ability to pay (p. 4) and adds, generally, that it would be extremely difficult to establish an appropriate level of price across the Community, as the choice of a low level would benefit immediate health care expenditure objectives but would provide a steady diminution of Europe’s contribution to global pharmaceutical R&D investment, and the choice of a high level would have the effect of reducing access to care by consumers and payers in countries where economic and social conditions mean that such prices cannot be afforded (p. 11).’

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79 Paragraph 164
80 Paragraph 167
81 Paragraphs 171-172
82 Paragraph 179
In response to the claim by GSK that the Commission had failed to show any other negative effect on competition resulting from Clause 4, the CFI pointed out that the Commission had (albeit briefly, yet adequately), concluded that the welfare of final consumers had been reduced by preventing them from taking advantage, in the form of a reduction in prices and costs, of the participation of the Spanish wholesalers in intrabrand competition on the markets of destination of the parallel trade originating in Spain. In the context of the products in question, the CFI recognised that for most products, the social security systems of the purchasing Member States should properly be considered as final consumers (in addition to a limited number of patients). The CFI noted, at paragraph 187 of its judgment, that GSK:

‘…acknowledged at the hearing that Clause 4...although mainly intended to prevent the transfer of surplus to the wholesalers, might have the effect of reducing the admittedly restricted benefit which their participation in competition provides for the final consumer on the markets of destination of the parallel trade.’

The Court concluded its analysis of GSK’s challenge to the Commission’s reasoning on anti-competitive effect in the following way:

‘190 ...it must be concluded that the Commission was entitled to find, in the light of elements whose relevance has not been validly called into question by GSK, that Clause 4...had the effect of reducing the welfare of final consumers by preventing them from taking advantage, in the form of a reduction in prices and costs, of the participation of the Spanish wholesalers in intrabrand competition on the national markets of destination of the parallel trade originating in Spain.

191 None of GSK’s arguments appears to be capable of upsetting that conclusion.

192 In particular, its fundamental argument that Clause 4 of the General Sales Conditions is justified because it would neutralise a distortion of competition attributable to the Kingdom of Spain is unfounded. The fact that the legal and economic context in which undertakings operate contributes to restricting competition cannot lead to acceptance of conduct on the part of those undertakings which, by preventing or restricting the competition which that context allows to subsist or to arise, in turn infringes the competition rules (Suiker Unie and Others v Commission, paragraph 56 above, paragraph 620, and CIF, paragraph 66 above, paragraph 57).

193 It follows from the foregoing that GSK has not succeeded in calling in question the Commission’s conclusion that the General Sales Conditions constituted an agreement within the meaning of Article 81(1) EC.

194 It also follows that, although the Commission’s principal conclusion that Clause 4 of the General Sales Conditions has as its object the restriction of competition is incorrect, GSK has not succeeded in calling in question its subsidiary conclusion that that provision had the effect of depriving final consumers of the advantage which they would have derived, in terms of price and
costs, from the participation of the Spanish wholesalers in intrabrand competition on the national markets of destination of the parallel trade originating in Spain.’

Article 81(3)

8.33 The Court set out the following at paragraphs 233 and 234 of its judgment:

‘233 Any agreement which restricts competition, whether by its effects or by its object, may in principle benefit from an exemption (Consten and Grundig v Commission, paragraph 110 above, pp. 342, 343 and 347, and Case T-17/93 Matra Hachette v Commission [1994] ECR II-595, paragraph 85)...

234 The application of that provision is subject to certain conditions, satisfaction of which is both necessary and sufficient (Remia and Others v Commission, paragraph 57 above, paragraph 38, and Matra Hachette v Commission, paragraph 233 above, paragraph 104). First, the agreement concerned must contribute to improving the production or distribution of the goods in question, or to promoting technical or economic progress; second, consumers must be allowed a fair share of the resulting benefit; third, it must not impose on the participating undertakings any restrictions which are not indispensable; and, fourth, it must not afford them the possibility of eliminating competition in respect of a substantial part of the products in question.’

8.34 At paragraphs 258 and 259 of its judgment, respectively, the CFI recited briefly the arguments of GSK put before the Commission to show i) that parallel trade in medicines marketed in Spain by it entailed a loss in efficiency and ii) that Clause 4 would lead to a gain in efficiency (a further analysis of the arguments of GSK and the views of the Commission followed later). The Court then concluded84 that the Commission’s analysis of the evidence and those arguments was insufficient to support the Commission’s conclusions (that GSK had failed to prove i) and ii) above) and, consequently, that it had failed to properly consider GSK’s request for an exemption under Article 81(3) EC.

8.35 The Court referred85 to Commission Communication COM(1998) 588 final and, among other points, cited the following assertions:

‘the pharmaceutical industry is based on research (pp.3 and 11) and it is clear that in the patented medicines sector there is very fierce competition in terms of innovation (p.16), which leads to a continuous flow of new products on the market (p.11); on the other hand, there is relatively little dynamic competition on prices after the products have been launched (p.16), there are important differences between Member States from the point of view of prices, which can be explained by a number of factors; one of the factors responsible for those difference appears to be the extent to which Member States

84 Paragraph 262
85 Paragraph 264
rely on price control, although there are also conjunctural factors such as inflation and currency fluctuations (p.4),

the pharmaceutical companies charge different prices [in different Member States] to take account of the differences in the ability to pay (p.4).

8.36 The view of the CFI was that the assertions of the Commission corroborated a part of the arguments of GSK and of the economic analyses in the supporting evidence, ‘…thus attesting to their reliability and credibility.’ It went on to say:

‘In its answers to the written questions put by the Court, the Commission stated that Communication (1998) 588 final…also indicated that in spite of important differences in prices between Member States, it was necessary to adopt an approach consistent with the principles of the single market, which made it impossible to justify measures the effect of which would be to maintain or increase the partitioning of the common market along national lines (p.18). The Commission further explained that the decision was consistent with that approach. However, that argument cannot be accepted. It presumes that an agreement providing that patented medicines reimbursed by the national sickness insurance schemes will be sold at different prices on different geographic markets, according to the preferences of the final consumer who bears the cost, cannot be granted an exemption in any circumstances. Article 81 EC makes no such provision.’

**Commission Decision 2006/857/EC – CFI case T-321/05 challenge**

8.37 On 15 June 2005 the Commission adopted a Decision, addressed to AstraZeneca AB (a Swedish company) and AstraZeneca Plc and fining them a total of €60million, concerning their breaches of Article 82 EC Treaty and Article 54 of the EEA Agreement (the EEA Agreement equivalent of Article 82 EC Treaty). This was the first Commission decision under Article 82 EC Treaty in the pharmaceutical drugs sector.

8.38 The Commission determined the relevant market to be national markets for proton pump inhibitors (‘PPIs’) sold on prescription and that AstraZeneca held a dominant position on the PPI market in a number of different Member States and Norway during different periods.

8.39 In its Decision, the Commission found two infringements of the provisions identified above.

‘The first infringement

The first infringement... consists of a pattern of misleading representations made by AZ before patent offices...and before national courts...

The misleading information was initially provided by AZ in the context of its applications to several patent offices in June 1993 and December 1994 within the

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86 Paragraph 266
EEA for extra protection for omeprazole (the active substance in [AstraZeneca’s] product Losec in the form of so-called supplementary protection certificates.

The second infringement

The second infringement...consists of [AstraZeneca’s] requests for the surrender of its market authorizations for Losec capsules in Denmark, Norway and Sweden combined with its withdrawal from the market of Losec capsules and launch of Losec MUPS tablets in those three countries.'

8.40 An EC press notice released on the same day as the Decision87 included the following statement from Competition Commissioner Neelie Kroes:

'I fully support the need for innovative products to enjoy strong intellectual property protection so that companies can recoup their R&D expenditure and be rewarded for their innovative efforts. However, it is not for a dominant company but for the legislator to decide which period of protection is adequate. Misleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules. Health care systems throughout Europe rely on generic drugs to keep costs down. Patients benefit from lower prices. By preventing generic competition AstraZeneca kept Losec prices artificially high. Moreover, competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals.'

8.41 The press notice expanded on the nature of the breaches as set out in the Decision published in the Official Journal. It stated that the misleading information given by AstraZeneca to several national patent offices in the EEA resulted in it obtaining supplementary protection certificates (‘SPCs’), granting it extended patent protection for Losec. It said also AstraZeneca selectively de-registered marketing authorisations for Losec in certain countries, with the intent of blocking or delaying entry by generic firms and parallel traders (who would rely on the existence of a marketing authorisation for the original corresponding product in order to market their products). As stated in the press release, subsequent changes in the applicable EC legislation have made impossible a repeat of the practice of AstraZeneca.

8.42 By an application lodged with the court on 25 August 2005,88 Astra Zeneca is challenging the Commission Decision. The case is still pending.

88 CFI Case T-321/05