

## **Complete Guide to the 2009 PPRS, NICE & other Pharmaceutical Cost Containment Measures in the United Kingdom**

Donald Macarthur

[don.macarthur@btinternet.com](mailto:don.macarthur@btinternet.com)

[www.justpharmareports.com](http://www.justpharmareports.com)

In an otherwise volatile pharmaceutical world, 2009 has seen two notable and durable anniversaries, the implementation of the tenth re-negotiated Pharmaceutical Price Regulation Scheme in January and the tenth birthday of the National Institute for Health and Clinical Excellence in April. PPRS and NICE, are among abbreviations most widely recognised, but their structures, functions and ways of working are often less than fully understood.

**‘Complete Guide to the 2009 PPRS, NICE & other Pharmaceutical Cost Containment Measures in the UK’** delivers what it says in the title. It provides in one place fully-researched, up-to-date information and interpretation on all the market access barriers facing pharmaceutical companies in the four countries that make up the United Kingdom.

The UK has a much bigger global impact in pricing and health technology assessment terms than its market size would suggest. It is a key lead-off one for launches. While accounting for less than 4% of world demand for prescription medicines, other countries that set prices with reference to those in the UK together account for 25% of that demand. Like them or hate them, the PPRS and NICE are original, well-established and influential models that governments and industry bodies elsewhere look to.

The report addresses:

- The UK’s complex decision-making processes for funding of medicines.
- The procedures and outcomes of the three HTA bodies, NICE, SMC and AWMSG.
- How and why the 2009 PPRS evolved in the way it did, and what this means for companies selling medicines to the NHS.
- The pros and cons of joining the voluntary or alternative statutory scheme.
- All the changes in the new PPRS and the prospects for the more novel but contentious parts, including flexible pricing, patient access schemes and generic substitution.
- What jargon including ‘end-of-life treatment’, ‘horizon scanning’, ‘NICE blight’, ‘OFT wedge’ ‘outturn’, ‘QALY’, ‘safety value’ and ‘top-up’ actually mean.
- Other cost containment measures impacting on prescribers, patients and the distribution chain.

[Order your copy of this essential new report now at www.justpharmareports.com.](http://www.justpharmareports.com)

### **Table of Contents**

Executive Summary

## Introduction

### **1. Health Service**

- 1.1 Organisation of the NHS
  - 1.1.1 NHS England
  - 1.1.2 NHS Scotland
  - 1.1.3 NHS Wales
  - 1.1.4 NHS Northern Ireland
- 1.2 Financial Flows
  - 1.2.1 Primary Care Prescribing in England
  - 1.2.2 Secondary Care Prescribing in England
  - 1.2.3 Other Countries
- 1.3 Outcomes

### **2. Pharmaceutical Market**

- 2.1 Overall Costs
  - 2.1.1 England
  - 2.1.2 Scotland
  - 2.1.3 GP Prescribing Costs
  - 2.1.4 Hospital Prescribing Costs
- 2.2 Players
  - 2.2.1 Manufacturers
  - 2.2.2 Wholesalers
  - 2.2.3 Community Pharmacies
  - 2.2.4 Hospital Pharmacies
  - 2.2.5 Dispensing Doctors

### **3. Health Technology Assessment**

- 3.1 England
  - 3.1.1 Topic Selection
  - 3.1.2 Technology Appraisal Process
  - 3.1.3 Clinical Guidelines
  - 3.1.4 Manufacturer Submission
  - 3.1.5 Appraisal Outcome
  - 3.1.6 Appeals
  - 3.1.7 Uptake of Recommendations
  - 3.1.8 Consultancy Services
  - 3.1.9 End-of-Life Treatments
  - 3.1.10 Further Reforms
- 3.2 Scotland
- 3.3 Wales
- 3.4 Northern Ireland

### **4. Principles, Evolution and Contents of the PPRS**

- 4.1 Historical Development
- 4.2 Parties to the PPRS
- 4.3 Eligibility for Membership
- 4.4 Objectives
- 4.5 Principles
- 4.6 Launch Pricing

- 4.7 Profit Assessment
  - 4.7.1 Annual Financial Return
  - 4.7.2 Return on Capital
  - 4.7.3 Return on Sales
  - 4.7.4 Outcome
- 4.8 Transfer Prices
- 4.9 Costs and Allowances
- 4.10 Price Reductions
- 4.11 Price Increases
- 4.12 Products Sold On
- 4.13 Appeals
- 4.14 Compatibility with European Law

## **5. Critique of the PPRS**

- 5.1 Office of Fair Trading Review
- 5.2 Strengths and Weaknesses
  - 5.2.1 Advantages
  - 5.2.2 Drawbacks
- 5.3 Reports to Parliament on PPRS
- 5.4 GSK vs Department of Health at High Court

## **6. Transition to 2009 PPRS**

- 6.1 Negotiation Principles
- 6.2 Industry's Starting Position and Strategy
- 6.3 Steps to Negotiate the 2009 PPRS
- 6.4 Reaction
  - 6.4.1 Manufacturers
  - 6.4.2 Wholesalers

## **7. Novel Features of the 2009 PPRS**

- 7.1 Central Role of NICE
- 7.2 Unified Horizon Scanning Process
- 7.3 Flexible Pricing
- 7.4 Patient Access Schemes
- 7.5 Prescribing Incentives
- 7.6 Greater Attention to Prices in the Hospital Sector
- 7.7 Generic Substitution
- 7.8 Statutory Price Control
- 7.9 Wholesale Margin

## **4. Other Types of Product**

- 8.1 Generics
  - 8.1.1 Generic Prescribing
  - 8.1.2 Generic Reimbursement
  - 8.1.3 Branded Generics
- 8.2 Parallel Imports
  - 8.2.1 PL(PI) Scheme
  - 8.2.2 Savings
  - 8.2.3 PIs and the PPRS
- 8.3 OTC Medicines

## **9. Other Cost Containment Measures**

### 9.1 Supply-side Controls: Impact on the Distribution Chain

#### 9.1.1 Payment to Wholesalers

#### 9.1.2 Payment to Pharmacies

##### 9.1.2.1 Remuneration

##### 9.1.2.2 Reimbursement

#### 9.1.3 Payment to Dispensing Doctors

### 9.2 Value-added Tax

### 9.3 Demand-side Controls: Impact on Prescribers and Patients

#### 9.3.1 Prescribing Controls

#### 9.3.2 Prescribing Advice

#### 9.3.3 Incentives for Prescribing Savings

#### 9.3.4 Patient Co-payment

#### 9.3.5 Top-up Payments

## **List of tables**

2.1 Estimated cost of prescribing by English SHA

2.2 Annual change in cost of prescribing by GPs vs hospital doctors

2.3 Expenditure on types of medicines by country in primary care

2.4 Expenditure on types of medicine by country in secondary care

2.5 Share of distribution to community pharmacies

2.6 Principal pharmacy chains

3.1 Comparison of NICE's MTA and STA processes

3.2 Technology not recommended for use by NICE

3.3 NICE's decisions and cost per QALY

4.1 ABC Pharmaceutical Co: Assessment of profit under PPRS

4.2 Examples of costs and activities that qualify for PPRS allowances

4.3 Number and value of price increases under PPRS

6.1 Bilateral comparison of ex-manufacturer prices, 1995-2006

6.2 Negotiation/implementation timetable for 2009 PPRS

7.1 Examples of patient access schemes in UK

7.2 Direct-to-pharmacy distribution schemes in UK

7.3 Restricted wholesaler schemes in UK

8.1 Generic prescribing & dispensing by Rx items, England, 1996-2007

8.2 Generic prescribing & dispensing by NIC, England, 1996-2007

8.3 Evolution of parallel import penetration, 1998-2008

8.4 Impact of price modulation in 2005 PPRS on PI penetration

9.1 Typical wholesaler discount structure to independent pharmacies

9.2 Fees for dispensing doctors

References

Glossary of Acronyms and Abbreviations

Appendix 1: Comparison of the four most recent PPRS agreements

Appendix 2: Responsibilities and contact details of Department of Health's PPRS staff