Presented at the PPRI Conference, 29-30 September 2011, Vienna, Austria

LITERATURE REVIEW ON PATIENT ACCESS SCHEMES, FLEXIBLE PRICING SCHEMES AND RISK SHARING AGREEMENTS FOR MEDICINES

Ruth Puig-Peiró, Jorge Mestre-Ferrandiz, Jon Sussex and Adrian Towse, Office of Health Economics

Objectives

To identify existing knowledge about the costs and benefits, assessed either quantitatively or qualitatively, of performance based reimbursement, risk sharing schemes, patient access schemes, and flexible pricing schemes for pharmaceuticals

Methods

A systematic literature review was conducted using PubMed for the period January 2008 - April 2011.

The terms “risk sharing”, “flexible pricing”, “patient access schemes”, and “performance-based reimbursement” were searched in titles and abstracts

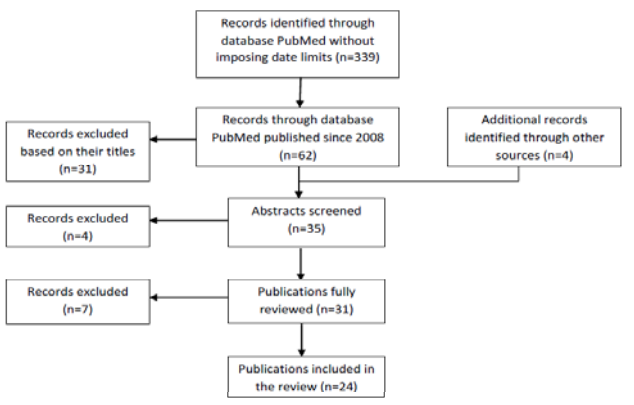
Definitions:

Risk sharing: A contract between manufacturer and payer that reduces the payer’s financial risk through linking P&R conditions to real life effectiveness or utilization of the health technology

Flexible pricing (UK-specific): Process involving an adjustment (up or down) to UK list prices on the basis of new evidence on clinical and cost-effectiveness or a different indication being developed

Patient access (UK-specific): Intended to be used when NICE has turned down use of a product by the NHS. Patient access schemes are initially negotiated between the company and the DH and then referred to NICE for a review of potential use by the NHS in England and Wales

Figure 1. Flow diagram of study selection process.



Main results

• More than 40 per cent of the publications referred to the Multiple Sclerosis Risk Sharing Scheme (MS RSS) implemented in the UK since 2002
• The review did not identify any cost benefit analysis evaluating the overall economic impact of schemes in monetary terms. All included studies discussed costs and benefits qualitatively and in some cases, when known, some costs were reported
• Key stakeholders participating in the schemes (patients, payers, providers and industry) bear different costs and benefits and conflicting incentives may arise
• Costs and benefits vary widely depending on the characteristics of the scheme. Financially based schemes are easier and faster to implement than outcome based schemes which are more complex and therefore suffer from higher uncertainty about the overall balance of costs and benefits

Benefits and costs identified from the literature

	Benefits	Costs
Patients	Access to new treatments where otherwise that would have been difficult Increased treatment options and potential health improvement	When patients are excluded from the scheme for not meeting the studies’ inclusion requirements
Providers	Increased knowledge in the management of the disease More qualified clinical staff Increased clinical research opportunities Spillover effects in the treatment of other disease areas	Capacity constraints due to the need for more clinical staff Data entry requirements and follow up of patients can be burdensome
Payers	Improved patients’ health Paying a price closer to the value of the drug (a ‘’value-based” pricing approach) Reduced uncertainty about the drug’s effectiveness Patients better targeted Decision-making based on scientific evidence Attractive discounts and better management of budgets Potential cost savings	Opportunity costs of health system resources Transactional costs (negotiation, contracting, monitoring and data collection and analysis) Potential for gaming by manufacturers Administrative burden Time elapsed Enforceability of the contractual agreement Difficult to withdraw technologies proven not effective Uncertainty around results if methodology has important limitations Higher actual expenditure than budgeted
Industry	Reward innovation Stimulate R&D Increase coverage Guarantee uptake of new and expensive drugs	Transaction costs Time elapsed Risk of not showing any additional effectiveness
	Increase returns to investment Competing drugs might enter the market faster	

Conclusions

• There is lack of consensus on the welfare consequences of the schemes and their social desirability, partly explained by the scarce evidence available.
• Some authors recommend outcome-based agreements only in exceptional cases given their complexity and high costs, in line with the recommendations in the PPRS (2009).
• Identified benefits are countered by significant costs and challenges and therefore the overall balance remains unclear, despite strong opinions regarding one specific scheme (the MS RSS).
• Important lessons are to be learned from the existing experience, but further objective research is necessary for two main reasons:

a) to assess in a transparent way to what extent the transactional costs and administrative burden of the schemes are shared between the payers and the pharmaceutical companies as they constitute an important barrier for the implementation of the schemes
b) to aid design of a successful Value Based Pricing (VBP) system for new drugs in the UK in the next few years, given the similar principles that underpin outcome-based schemes where prices are set to match “real world” NHS value in practice

Financial support: The Office of Health Economics (OHE) receives research funding from the Association of the British Pharmaceutical Industry (ABPI). No separate funding was received for this paper. The views expressed in this paper are the authors and do not represent those of either the OHE or the ABPI. For further information, contact jmestre-ferrandiz@ohe.org