

Risk sharing schemes

— improving patient access to new drugs

By Kevan Wind, MRPharmS

Operational issues are arising in the NHS as a result of the pharmaceutical industry's development of risk-sharing schemes for high cost medicines. The introduction of Janssen-Cilag's Velcade (bortezomib) response scheme has attracted publicity (*The Pharmaceutical Journal* 2007;279:461), and similar schemes are proposed for Pfizer's Sutent (sunitinib) and Roche's Tarceva (erlotinib).

The schemes are designed in the main to support patient access to new drugs in the transitional period between the grant of a marketing authorisation by the Medicines and Healthcare products Regulatory Agency and the accrual of sufficient outcome-based trial data for organisations such as the National Institute for Health and Clinical Excellence to review the drug's comparative place in treatment.

Risk-sharing or rebate schemes (also called patient access schemes) allow a manufacturer to maintain a global market price but also reach the NICE threshold for price per quality adjusted life year. The concept is that payment for a treatment will be deferred or refunded if it can be shown to have been ineffective in a specific patient. Thus the NHS only pays where patient benefit accrues.

These schemes should allow greater access to medicines and may speed their uptake — something that the NHS has been accused of failing to manage. They are by definition value-based and give

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transparency to outcomes. However, they require potentially burdensome administration and their introduction is complicated by the variety of funding arrangements possible, each of which has specific implications.

Most of the funding methods create a complex audit trail. Many are labour intensive for pharmacy staff (eg, by involving multiple computer entries), and some are labour intensive for clinical and financial staff.

— Pros and cons

The potential advantages of risk-sharing schemes include the following:

- Medicines are made available in the global arena of linked market prices but with localised cost-effectiveness targets
- Healthcare should improve, with the right patient being treated at the right time
- Speed of uptake of new medicines should improve
- The system is value-based
- Outcomes of treatment will be in the public domain
- Sales of medicines will increase and manufacturers' profitability should improve
- Opportunities for partnerships between industry and the NHS will increase

Potential problems include the following:

- The potential administrative burden
- Financial flows in the NHS are complex and there is a need for reconciliation between the risk-sharing scheme and the movement of funding between the suppliers, providers and commissioners

- Schemes may require the transfer of individual patient data (with implications for confidentiality)
- Auditing of the schemes may be complex because all sides need to be assured of fairness
- Mechanisms need to be agreed for measuring clinical criteria
- Specific objective measures of clinical response are not available for all treatments
- As clinical experience grows and patient response rates improve, the return to the NHS could fall
- The patient response rates will not be consistent across the NHS (eg, tertiary centres treat resistant patients)
- Clinicians may treat more freely with medicines they perceive to be free
- Abuse of the schemes by all parties is possible

— Recommendations

To reduce the disadvantages of risk-sharing schemes and maximise the potential benefit for patients, the NHS and industry, the following features are recommended:

Simplicity Schemes should be patient-centred, with patient agreement, and based on easily measured clinical outcomes.

One model To reduce administrative burdens, all schemes should comply with a single preferred model.

Communication Schemes must be jointly developed between the NHS (providers and commissioners) and industry.

Infrastructure costs The costs required to administer the schemes must be factored in for all participants (providers may need a data manager).

Financial clarity Schemes must address the twin issues of reconciliation of patient outcomes with financial flows back to commissioners. Financial flows within trusts must also be accommodated and prices paid not vary. Ideally the payments to industry should be deferred until the decision to continue treatment is made.

Registration Before commencing treatment, patients should be registered with all three participants in the scheme (providers, commissioners and manufacturers).

— Summary

Risk sharing schemes are not new, but have recently undergone something of a renaissance. While these arrangements can improve the speed of access to new medicines, they need to be managed correctly to ensure that they do not become a burden to healthcare systems.

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Position statement

The Cancer Networks Pharmacy Forum has published a position statement on risk-sharing schemes, endorsed by the British Oncology Pharmacy Association. It is available at www.bopawebsite.org