



# **Cancer Network Pharmacists Forum**

## **Position Statement on “Risk Sharing” Schemes in Oncology**

**Endorsed by BOPA for use in NHS England**

## Document Control

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## Executive Summary

CNPF and BOPA members welcome and are committed to actively supporting any initiatives that improve access to new medicines for NHS patients. It is essential, however, that the benefits and costs of initiatives such as offers to NHS of risk-sharing schemes by pharmaceutical manufacturers are assessed as carefully as those of the medicines themselves and to ensure that the schemes genuinely offer the NHS value-for-money. CNPF and BOPA will work with all stakeholders to achieve this. Risk sharing schemes are multiplying rapidly, are not consistent in the way they work, and this lack of consistency increases the financial, administrative and governance risks to NHS organisations. We have produced this position statement to provoke wider debate around these risks at both local and national level. We also make the following recommendations on the management of these risks.

## Management of Financial Risks

1. Provider Trusts should not enter into any agreement to participate in a risk sharing scheme without discussion with the relevant commissioning PCT(s) and agreement on the financial re-imburement mechanisms to be employed.
2. Provider Trusts using these schemes must develop robust processes to ensure expenditure reporting is accurate, that PCT's receive any applicable discount/refund and that all payments and refunds can be reconciled.
3. At present any risk sharing scheme should offer a number of options for claiming discounts/refunds - such as cash-back, credit note, free product – in order to allow local flexibility.
4. Provider Trusts should ensure that reference costs are collected in such a way that the actual chemotherapy expenditure is recorded. Basic procurement costs derived from pharmacy stock control systems may not be an accurate measure of chemotherapy expenditure if refunds are not also recorded on the pharmacy system.
5. In order to ensure the integrity of the forthcoming chemotherapy Healthcare Resource Groups (HRG's), provider Trusts should ensure that any discount/refund on a particular product is reflected in the expenditure of that particular product and not in other budgets or on drugs/ regimens in different HRG bands.
6. Non drug-specific refunds have the potential to unbalance the HRG's and this mechanism of refund should not be offered by industry or accepted by the NHS. Refunds should only be attributed to the specific product initially used.

### Management of Administrative Risks

7. Industry should ensure that no patient-identifiable information is requested and provider Trusts should ensure that no such data is shared as part of these schemes.

8. Provider Trusts should ensure that data is collected by the most relevant professional during normal clinical practice. However, in view of the number of these schemes, some provider Trusts should consider the need to recruit staff specifically to collect and report the necessary data and how this will be funded.

### Management of Governance Risks

9. Any discounted price should be made known to NICE to allow it to be reflected as part of their appraisal process.

10. The DH should develop a position on whether risk sharing schemes offered only as an interim measure are acceptable.

11. Individual NHS organisations should set clear principles for defining acceptable risk-sharing schemes to ensure a consistent local approach to the various schemes. The DH may wish to support development of clear principles for NHS-wide adoption.

12. Industry should offer these schemes across the NHS and not target them to specific organisations. The DH may also wish to consider whether schemes that are targeted only to specific organisations are acceptable. NHS organisations reviewing a particular scheme should assure themselves that the scheme is being offered NHS wide.

13. In the event of a negative NICE appraisal or of a risk sharing scheme being withdrawn, patients already receiving the product should have the option to continue therapy at the discounted price, until they and their clinicians consider it appropriate to stop. Schemes should be re-evaluated by NHS organisations following negative NICE appraisal.

14. As part of their decision-making process about adoption of a scheme, NHS organisations must be clear how they would manage a sudden price rise or closure of the scheme, with or without NICE approval of the product. This management plan should include consideration of how the issues will be communicated to all eligible patients.

15. Provider Drug and Therapeutic Committees (DTCs), in liaison with PCTs, should ensure that decisions about participation in these schemes are made only via an established single local mechanism for the local approval of all new medicines.

16. NHS organisations which explicitly state that consideration of “cost-effectiveness” is part of their decision-making process should ensure, as far as possible, that the cost-effectiveness of products being considered for use within a risk sharing scheme is evaluated as robustly as it is for all other products.

## **1. Background**

### **1.1 Drug Pricing in the UK**

Drug prices are currently controlled by the Pharmaceutical Price Regulation Scheme (PPRS). This system was set up principally to tackle primary care pricing, and therefore its main focus is on 'Branded drugs' and on profit controls. The PPRS limits changes in prices once a drug is marketed. In January 2007 the Office of Fair Trading published a detailed report<sup>1</sup> proposing that a value based approach to medicines pricing should replace the PPRS in the UK.

A working party has jointly been established by government and industry to consider options for reform of the PPRS. It is understood that the Department of Health (DH) has recently sent out a letter serving a 6-month notice stating that the current PPRS will be replaced on the 1st of September 2008<sup>2</sup>. The Health Select Committee recently published a report on the National Institute for Clinical Excellence (NICE)<sup>3</sup> which recommended that risk-sharing schemes should be used with caution. It was noted however that these schemes should not be used as a catch-all in cases of uncertainty over a drug's benefit. The DH response to this report is expected imminently.

### **1.2 Pharmaceutical Companies Position**

In the meantime, the pharmaceutical industry insists that it cannot directly lower UK prices for new agents due to multi-national pricing strategies and lack of flexibility at corporate level. The UK is seen by industry as a small market whose prices must be in line with Europe and the USA. The UK on its own accounts for circa 3.45% of world pharmaceutical sales.<sup>1</sup> Approval by the DH of the Velcade Response Scheme (VRS) as part of the NICE consideration of bortezomib (Velcade) for the treatment of multiple myeloma<sup>4</sup> appears to have been interpreted by the industry as a general endorsement of the "risk sharing" approach. This has resulted in an increasing number of schemes being proposed as a means of potentially securing entry of new drugs into the challenging UK market.

It must be noted that the Scottish Medicines Consortium (SMC) at present do not consider such pricing schemes when appraising new medicines.

### **1.3 Pricing Schemes in Oncology**

At the time of writing this position statement we are currently aware of six schemes that have been offered to the NHS and a number of additional proposed schemes that have been discussed with NHS organisations (see section 2). This highlights one of the main issues - that these schemes are multiplying rapidly, are not consistent in the way they work, and that this lack of consistency increases the financial, administrative and governance risks to NHS organisations. It should be noted that, to date, only the VRS, has been endorsed by the DH and that this occurred in the context of a NICE appraisal. At this stage the DH are not planning to give guidance or direction on the adoption of schemes outwith the context of a

NICE appraisal and believe it is appropriate that individual NHS organisations decide whether or not they wish to participate in such schemes.

The ABPI has been asked to produce some good practice guidance for industry on preparing and administering schemes but this is likely to take some time due to competing commercial interests. We have produced this position statement in order to inform this process and to provoke wider debate around the issue.

#### **1.4 The position of CNPF and BOPA**

CNPF and BOPA members welcome and are committed to actively supporting any initiatives that improve access to new medicines for NHS patients. It is essential, however, that the benefits *and costs* of initiatives such as offers to NHS of risk-sharing schemes by pharmaceutical manufacturers are assessed as carefully as those of the medicines themselves and to ensure that the schemes genuinely offer the NHS value-for-money. CNPF and BOPA will work with all stakeholders to achieve this.

**2. Currently Available Risk Sharing Schemes**  
**2.1 Summary Table**

Drug	Indication	Scheme Title	Method of Application
Bortezomib (Velcade)	Multiple Myeloma	Velcade Response Scheme (VRS)	DH-approved deal. Offered to NICE and will be reviewed as part of NICE review. Buy drug at full cost – then retrospectively claim for replacement drug/ credit/ cash for non-responders.
Erlotinib (Tarceva)	NSCLC	Tarceva Access Programme (TAP)	Interim measure until final guidance from NICE. Programme not offered to NICE – NICE reviewing based on full list price. Rebate in form of credit note against any future Roche purchase. Rebate will provide drug acquisition parity compared to docetaxel for an average patient duration. Upper limit for number of packs set in business case and in contract.
Sunitinib (Sutent)	Metastatic RCC		Sunitinib in RCC currently being reviewed by NICE. Unclear if NICE review is based on full list price. First cycle free then 5% price reduction on further cycles.
Rituximab (Mabthera)	Follicular NHL	Maintenance Rituximab: Follicular Lymphoma In-licence Support Programme	Interim measure until final guidance from NICE. NICE reviewing based on full list price. Free drug (for the full licensed course) for the first 300 patients to sign up to the scheme.

<p>Cetuximab (Erbix)</p>	<p>Metastatic CRC</p>	<p>Cetuximab Cost Share Programme</p>	<p>Cetuximab reviewed and not recommended by NICE. Scheme independent of NICE. Rebate direct to PCT on the cost of any vials of Cetuximab used for patients who do not achieve a pre-agreed clinical outcome ('non-responders') at up to 6 weeks (up to an agreed maximum of 3200 milligrams).</p>
<p>Pemetrexed (Alimta)</p>	<p>Mesothelioma and NSCLC</p>		<p>Pemetrexed in NSCLC reviewed and not recommended by NICE. Pemetrexed in Mesothelioma has been approved by NICE. NICE reviews based on full list price. Receive a discounted price for drug after certain pre-agreed level of expenditure at full price has been reached. Company aim is to 'preserve' full price for mesothelioma patients and allow discount for NSCLC use.</p>

## 2.2 Examples of good practice

We would suggest that the currently available schemes can broadly be divided into two specific categories:

- Performance-based schemes – depend on ability to achieve a defined clinical result.
- Finance-based schemes – simply reduce the effective price of a drug and are not conditional on response.

In order to assist industry in an attempt to standardise risk sharing schemes, and their associated paperwork, we suggest that the Velcade Response Scheme (VRS), which has now been discussed widely with NHS professionals and adapted accordingly, may be a good example of how a performance-based scheme could be structured. It should be noted, however, that the VRS involves the use of very clear (and fairly immediate) response markers, which may not always be available. We would also propose the Sunitinib scheme as a good example model for a finance-based scheme.

As previously discussed, the number and variety of the current (actual and proposed) schemes has the potential to increase the financial, administrative and governance risks to individual NHS organisations and indeed the broader NHS. These risks are discussed in the next section.

### 3 Risks to the NHS from risk sharing schemes

#### 3.1 Financial Risk

##### 3.1.1 *Incorrect Trust Expenditure Reporting*

Unless discounts/refunds of any sort are reflected in the net price of all goods concerned at all times, so that all issues to all patients are priced correctly at the time of issue, achieving accurate retrospective reconciliation of costs and refunds to ensure an accurate bottom-line figure for treatment costs will inevitably generate sources of potential error and financial risk to the NHS. Many of the funding mechanisms associated with current schemes make accurate reconciliation and costing possible only at the expense of considerable extra workload for Trust finance and pharmacy staff. Significant risks are outlined below.

##### 3.1.2 *PCTs being reimbursed/ charged incorrectly*

How PCTs manage funding flows with Trusts will influence how retrospective reimbursement is managed and how it can be offset against agreed funding and be credited to the PCT. Invoices to PCTs raised by trust finance departments will presumably need to include details of any applicable scheme and how the discounts/refunds were applied or are to be applied.

#### **Recommendation**

Provider Trusts should not enter any agreement to use a risk sharing scheme without discussion with the relevant commissioning PCT(s) and agreement on the financial re-imburement mechanisms to be employed.

#### **Recommendation**

Provider Trusts using these schemes must develop robust processes to ensure expenditure reporting is accurate, that PCT's receive any applicable discount/refund and that all payments and refunds can be reconciled.

#### **Recommendation**

At present any risk sharing scheme should offer a number of options for claiming discounts/refunds - such as cash-back, credit note, free product – in order to allow local flexibility.

##### 3.1.3 *Unbalancing Payment by Results (PbR)*

The purpose of reference costs is to reflect how much a provider Trust has spent on a particular Healthcare Resource Group (HRG). In the case of the proposed cancer chemotherapy HRG's there is both a procurement and a delivery HRG. Chemotherapy treatments must have a procurement and a delivery (administration to the patient) HRG associated with each cycle, so even if the chemotherapy were to be procured at zero cost, the delivery HRG must still be applied so that activity is recognized and charged. If the overall chemotherapy expenditure of a Trust is reduced by risk sharing schemes then

this should be reflected in the reference costs and should apply whether the discount/refund is in the form of cash, credit note or replacement stock. The final reference cost collection exercise needs to accurately reflect the costs of chemotherapy procurement and treatment delivery. This raises specific issues with the two different categories of scheme.

### **3.1.3.1 Performance based schemes**

A number of issues may arise. As an example, if a provider Trust funds the drug initially and only applies to the PCT's for reimbursement of the cost upon confirmation of successful treatment then HRG's will be recorded for the procurement and administration of every cycle. However if treatment is unsuccessful and the provider Trust receives a refund from the manufacturer which is not spent on chemotherapy or is not reflected in the chemotherapy budget then the reference costs will be higher than the actual costs of chemotherapy. If the refund is spent on a chemotherapy regimen in a different band to that of the original drug, then again there will be an imbalance in reference costs.

### **3.1.3.2 Finance based schemes**

These schemes tend to supply provider Trusts with product at discounted or zero price. As reference cost collection is an annual event then as long as the discount is reflected in the total chemotherapy procurement costs, the reference costs should reflect actual expenditure on chemotherapy. These schemes are less likely to unbalance the HRG's as the discount received is on the product used and the financial flows are easier to manage.

#### **Recommendation**

Provider Trusts should ensure that reference costs are collected in such a way that the actual chemotherapy expenditure is recorded. Basic procurement costs derived from pharmacy stock control systems may not be an accurate measure of chemotherapy expenditure if discounts/refunds are not also recorded on the pharmacy system.

#### **Recommendation**

In order to ensure the integrity of the forthcoming chemotherapy Healthcare Resource Groups (HRG's) provider Trusts should ensure that any discount/refund on a particular product is reflected in the expenditure of that particular product and not in other budgets or on drugs/ regimens in different HRG bands.

#### **Recommendation**

Non drug-specific refunds have the potential to unbalance the HRG's and this mechanism of refund should not be offered by industry or accepted by the NHS. Refunds should only be attributed to the specific product initially used.

## 3.2 Administrative Risks

### 3.2.1 *Sharing of patient-specific data*

Performance-based schemes may require a great deal of data collection and for sensitive information to be supplied to commercial companies. Companies may require detailed evidence of usage including patient identifiers, date of treatment, total dose(s) (mg) of drug given, purchase cost of drug per mg/vial (dependent on financial agreement), cost per cycle, total cycles, and any dose(s) that may have been prepared but not given.

#### **Recommendation**

Industry should ensure that no patient-identifiable information is requested and provider Trusts should ensure that no such data is shared as part of these schemes.

### 3.2.2 *Workload Implications*

We believe that these schemes will have a yet-to-be quantified but significant impact on provider Trusts as many will require collection and reporting a level of considerable detail to clarify the circumstances under which a claim is made. We agree with a previous DH position that these schemes “should as far as possible build on normal clinical practice without requiring elaborate additional infrastructure” and that “data entry should be as simple as possible and arise out of normal patient contacts”.<sup>5</sup>

#### **Recommendation**

Provider Trusts should ensure that data is collected by the most relevant professional during normal clinical practice. However, in view of the number of these schemes, some provider Trusts should consider the need to recruit staff specifically to collect and report the necessary data and how this will be funded.

### 3.3 Governance Risks

#### 3.3.1 Increased pressure on decision making processes

There appear to be three scenarios where risk sharing schemes are being proposed by industry:

1. Where the company wants to get a foothold in the market prior to a NICE appraisal and where competitor therapies are cheaper to procure.
2. Where a company wishes to reduce the cost per QALY after a negative NICE appraisal.
3. Where a company wishes to reduce the cost per QALY and allow the product to hit the NICE threshold(s) at the time of a Technology Appraisal.

It is clear that in both scenarios 1 and 2 the risk-sharing scheme is generally only an interim measure which is being offered for a limited time. Scenario 1 clearly contributes greatly to the already significant pressure on NICE to approve the use of that product – it allows patients and clinicians access to the product at a significantly reduced price whilst NICE appraises the same product at full list price – which the NHS will ultimately pay in the event of a positive NICE appraisal.

Scenario 2 clearly puts pressure on local NHS organisations to fund, at reduced price, the use of a product that has been turned down by NICE after consideration at full list price and where there is no long term guarantee of reduced price. NICE’s default position when carrying out appraisals is to use a products list price, however a recent draft consultation document<sup>6</sup> from them suggested that they may consider including price reductions in analyses in future:

“Analyses based on price reductions for the NHS will only be considered where the reduced prices are transparent, can be available consistently across the NHS, and where the period for which the specified price is available is guaranteed. In these circumstances, advice will be taken from Institutions such as the NHS Purchasing and Supply Agency (PASA) or Welsh Health Supplies. The review date for the appraisal will be informed by the period of time over which any such agreements can be guaranteed. “

#### **Recommendation**

Any discounted price should be made known to NICE to allow it to be reflected as part of their appraisal process.

#### **Recommendation**

The DH should develop a position on whether risk sharing schemes offered only as an interim measure are acceptable.

### 3.3.2 *Inequality of Access to New Medicines*

Due to the number, variety and complexity of issues described in this paper Networks, provider Trusts and Primary Care Trusts are taking different views on these schemes and therefore making conflicting decisions regarding access to these drugs for their patients. There appears also to be anecdotal evidence that individual NHS organisations are adopting certain schemes and not others.

An additional issue is that not all schemes may be offered to all Trusts or Networks across the NHS. It has been suggested that some potential schemes may be offered only to Trusts where the uptake of the drug is slow and not to Trusts where usage is as predicted or considered acceptable by the manufacturer. We would suggest that in reality this approach is ultimately likely to increase rather than decrease inequality of access throughout the NHS and between certain disease areas and should be strongly resisted.

The DH has developed some working principles to for guidance if it is approached to endorse a particular scheme in the context of a NICE appraisal<sup>7</sup>. *These principles do not represent formal DH guidance.* However we have adapted them and present them below to inform the setting of local principles. Schemes should be

- Operationally simple for the NHS without disproportionate additional costs and bureaucracy (e.g. introducing unnecessary tests or unduly complex monitoring / reimbursement processes).
- Clinically robust, appropriate and monitorable (e.g. if it is a responder scheme, there must be a relatively straightforward way to measure a patient's clinical response).
- Consistent with existing financial flows in the NHS (e.g. the effective price must be transparent to payers and consistent with local commissioning, so the costs and savings accrue to local services who are making commissioning and treatment decisions)
- Capable of delivering value: capable of inclusion in submissions to local decision making groups and subject to their views on cost-effectiveness (this ensures that schemes really do deliver value for money). Clarity is also required on the exact duration of any agreement and the circumstances under which it might be terminated.

#### **Recommendation**

Individual NHS organisations should set clear principles for defining acceptable risk-sharing schemes to ensure a consistent local approach to the various schemes. The DH may wish to support development of clear principles for NHS-wide adoption.

### **Recommendation**

Industry should offer these schemes across the NHS and not target them to specific organisations. The DH may also wish to consider whether schemes that are targeted only to specific organisations are acceptable. NHS organisations reviewing a particular scheme should assure themselves that the scheme is being offered NHS wide.

### **3.3.3 Risk of discontinuation of therapy**

As discussed above, it is clear that many of these schemes are “interim” measures only and this raises a significant risk for NHS organisations – that in the event of NICE not recommending the product, or of the risk-sharing scheme being withdrawn and the full list price being charged, the organisation is left to manage the costs of patients already receiving treatment and identifying appropriate alternatives for those who might otherwise have expected to be treated with the product in future.

If local funding of the product is conditional on a specific pricing condition, it follows that funding could be expected to cease were that condition no longer met. NHS organisations should, as part of the process of adoption of these schemes, ensure there is a management plan in place to manage a sudden price rise or closure of a scheme. There should also be an explicit agreement between the NHS organisation and the Pharmaceutical Company regarding scheme duration.

### **Recommendation**

In the event of a negative NICE appraisal or of a risk sharing scheme being withdrawn, patients already receiving the product should have the option to continue therapy at the discounted price, until they and their clinicians consider it appropriate to stop. Schemes should be re-evaluated by NHS organisations following negative NICE appraisal.

### **Recommendation**

As part of their decision-making process about adoption of a scheme, NHS organisations must be clear how they would manage a sudden price rise or closure of the scheme, with or without NICE approval of the product. This management plan should include consideration of how the issues will be communicated to all eligible patients.

### **3.3.4 Inconsistency of approach**

NHS organisations are increasingly being challenged about their decision-making processes and it is increasingly clear that decisions must be seen to have been taken in a clear and transparent way and in accordance with established policies designed to promote robust assessment of safety, efficacy and cost-effectiveness of all new drugs. There is a risk that the offer

of a discount scheme may lead to decisions being made outside of established policies and, in particular, without robust review of the evidence for efficacy and cost-effectiveness of the drug concerned or prioritisation of funding for it against other competing priorities. Unless all decisions about funding for new drugs are subject to the same level of scrutiny and made by the same mechanisms, it will be impossible to demonstrate that all reasonable steps have been taken to assure equity of access.

**Recommendation**

Provider Drug and Therapeutic Committees (DTCs), in liaison with PCTs, should ensure that decisions about participation in these schemes are made only via an established single local mechanism for the local approval of all new medicines.

**Recommendation**

NHS organisations which explicitly state that consideration of “cost-effectiveness” is part of their decision-making process should ensure, as far as possible, that the cost-effectiveness of products being considered for use within a risk sharing scheme is evaluated as robustly as it is for all other products.

#### 4. Conclusions

There is an increasing number of risk-sharing schemes open to the NHS and planned for the near future. The use of risk-sharing schemes saves on drug acquisition costs but requires significant extra work from pharmacy and finance departments and from clinicians to ensure success. The costs of this work must be recognised and factored into the overall evaluation of the benefits offered to the NHS. The work and hence the costs can be minimised by dialogue and active collaboration between NHS and pharmaceutical manufacturers to design mutually acceptable schemes. Amongst other factors, a high level of consistency between schemes will be critical to NHS acceptability. It is essential that the benefits and costs of initiatives such as risk-sharing schemes are assessed as carefully as those of the medicines themselves and to ensure that the schemes genuinely offer the NHS value-for-money. CNPF and BOPA will work with all stakeholders to achieve this.

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## Acknowledgements

This paper has been informed by a paper by Steve Williamson, Consultant Pharmacist. Uptake of pharmaceutical industry pricing strategies to enhance cost effectiveness and affordability. North of England Cancer Drug Approvals Group (NE CDAG). November 07.

