

**Cancer Network Pharmacists Forum  
Position Statement on Risk Sharing Programmes in Oncology/Haematology  
Response to Consultation Comments**

Consultee	Comments	Response
DH	<p>The statement that "risk sharing schemes are multiplying rapidly" would benefit from some qualification. To date only two such schemes (MS drugs and Velcade) have been endorsed by DH, both in the context of NICE appraisals. It is probably helpful to clarify that at this stage we are not planning to give guidance or direction on the adoption of schemes outwith the context of a NICE appraisal. If a company does propose a scheme in the context of a NICE appraisal, the Department will decide whether to ask NICE to consider it in the context of that appraisal. The various other schemes being offered by companies (e.g.prior to a NICE appraisal) do not, therefore, carry any DH endorsement, and we believe it is appropriate that individual NHS organisations decide whether or not they wish to participate in them.</p>	<p>1. Thank you. Section 1.3 has been updated to read: "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."</p>
	<p>Recommendation 9 - It might be worth cross-referencing NICE's policy on</p>	<p>2. Thank you. This supports our</p>

	<p>How it accounts for price in appraisals. NICE's default is to use list price, but the revised draft "Guide to the methods of technology appraisal" (currently out to consultation) says that:</p> <p>"Where the acquisition price paid for a resource may differ from the public list price (for example, pharmaceuticals and medical devices sold at reduced prices to NHS institutions), the public list price should be used in the reference-case analysis. Sensitivity analysis should assess the implications of variations from this price. 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."</p> <p>It is for drug companies to submit such information as part of an appraisal.</p>	<p>recommendation. We have added a note to state the proposed NICE position.</p> <p>However the point made is that these schemes are often "interim" in nature and are not being offered/submitted to NICE as part of the appraisal process. The CNPF/BOPA believe that these schemes should be offered to NICE if they are initially offered to the NHS.</p>
	<p>Recommendation 11 - DH has no plans at present to issue guidance to inform local decisions on such schemes. However you may find it helpful to see the "working principles" which we have developed to inform</p>	<p>3. Thank you. See point 1. CNPF and BOPA, however, will continue to make the case for some national consistency to these schemes which, we believe, would be helped by DH involvement.</p>

	<p>any national discussions on scheme proposals (i.e. were DH to be asked to endorse a particular proposal in the context of a NICE appraisal). These are appended below. I would be content for you to make reference to these if you think that would be helpful, though I should emphasise that they are working principles, not formal guidance, and they may evolve in the light of experience.</p>	<p>The working principles have been adapted and added to the statement, in the meantime, in order to assist local processes.</p>
	<p>Recommendation 14 - If a scheme has national endorsement in the context of a NICE appraisal, we would expect there to be an explicit commitment on scheme duration (as with the Velcade scheme). If a positive NICE appraisal is conditional on a specific pricing condition, it follows that its guidance could be expected to cease to apply were that condition no longer met.</p>	<p>4. Thank you. We agree. The point we are making, however, is regarding the “interim” nature of many of these schemes and the fact that only 1 of these scheme in oncology/haematology has this type of national endorsement. We have added a statement to say: “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. Their should also be an explicit agreement between the</p>

	<p>Para. 1.1 - you might want to reflect the recommendation of the recent Health Select Committee report on NICE, which broadly speaking urges a cautious approach to such schemes. The Department of Health will be responding to the Committee's report in the coming weeks (probably in March).</p>	<p>NHS organisation and the Pharmaceutical Company regarding scheme duration.”</p> <p>5. Thank you. The following statement has been added: “The Health Select Committee recently published a report on the National Institute for Clinical Excellence (NICE)<sup>2</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 Department of Health (DH) response to this report is expected imminently.”</p>
	<p>Para. 1.3 - might be helpful to distinguish here schemes offered locally and the two that have a national status.</p> <p>Para. 2.2 - There is no agreed categorisation for such schemes (and I am not familiar with the detail of the Sunitinib scheme) but would it be more accurate to describe two broad categories which (a) depend on ability to achieve a defined clinical result or (b) simply reduce the effective price of a drug and are not conditional on</p>	<p>6. See response 1.</p> <p>7. Thank you. The statement has been updated accordingly.</p>

	<p>response? Both of course have an impact on cost-effectiveness. It might be worth highlighting the fact that the Velcade scheme involves the use of very clear (and fairly immediate) response markers, which may not always be available.</p>	
Lilly UK	<p>The NICE guidance for the use of Alimta in Mesothelioma has now been published, recommending Alimta for the treatment of the condition. The document seems to have been drafted before the decision was announced - would it be possible to update this?</p>	<p>8. Thank you. The statement has been updated accordingly.</p>
Roche	<p>Recommendation 3: It may not be possible for manufacturers to offer multiple options for claiming rebates - it may create too much complexity in scheme administration, may not be logistically feasible and / or may not be supported by global parent companies.</p>	<p>9. Thank you. NHS organisations and their commissioning processes vary across NHS England. This recommendation recognises the fact that one system may not suit all. However we see this as an interim measure and would like the NHS and industry to work together to find a more consistent approach.</p>
	<p>Recommendation 6: This should be clarified to indicate that drug delivery, administration or service charges are <i>within</i> the scope of refunds as long as these relate to the particular drug regimen in question. This would be consistent with HRG payment</p>	<p>10. Thank you. Recommendation 6 does not address the issue of service delivery. It addresses the issue of how the effective price of the product is made transparent to payers and as part of the reference cost collection.</p>

	<p>mechanisms and is important in terms of providing scope for schemes to be viable.</p> <p>Recommendation 13: Any scheme should have a sunset 'exit' clause included within it and proposed by the manufacturer so that it is absolutely clear from the outset to all stakeholders if and how the scheme might be terminated and how changes to it would be managed.</p>	<p>11. Thank you. See response 4.</p>
Pfizer	<p>There is just one main point that we would like to comment on and suggest an amendment around section 2.2 That is that the 'Sutent 1<sup>st</sup> free cycle programme' is not actually a risk share scheme, but rather a move by Pfizer to help bring the SUTENT cost/QALY closer to current HTA thresholds in order that patients can get access to this treatment. This was created through a 5% price reduction of Sutent and the introduction of a 1<sup>st</sup> free cycle for all prescriptions in the UK.</p>	<p>12. Thank you. We have altered the wording of section 2.2 – see response 7. However we still believe that there are risks to NHS organisations with all these schemes (including the Sutent scheme) that need to be understood and managed by those organisations. In light of this and the fact that we feel inconsistency of approach to these schemes is the biggest risk to NHS organisations we would like to remain consistent in the broad term (risk sharing scheme) used.</p>
Network Pharmacist	<ul style="list-style-type: none"> <li>• It needs to be clear that CNPF is an NHS England group.</li> <li>• Target audience / circulation list All the health departments from the home countries as well as DH should be listed. Most of the</li> </ul>	<p>13. In light of feedback from Network Pharmacist colleagues in NHS Scotland and NHS Wales it was decided to rebadge this statement as a CNPF document endorsed by BOPA</p>

	<p>posts/organisations not recognisable in NHS Scotland.</p> <ul style="list-style-type: none"><li>• Recommendations</li></ul> <p>Specific references to DH, provider Trusts, provider DCTs, PCTs, NICE appraisals in all but two or three recommendation. Could be genericised by the use of 'Health Departments' and 'NHS organisations', 'national appraisals'.</p> <p>Suggest placing governance risks before financial risks as many of the latter are specific to England.</p> <p>NICE STAs do not apply in Scotland.</p> <p>No commissioning process in NHS Scotland or PbR.</p>	<p>for use in NHS England. We would be happy for colleagues in Scotland, Wales and Northern Ireland to adapt this document for use in those countries.</p>
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