Frank McAveety MSP
Convener
Public Petitions Committee
The Scottish Parliament
EDINBURGH
EH99 1SP

September 2008

Dear [Name],

Thank you for your letter of 18 June 2008 in which you provided the Committee’s report of its inquiry into the availability of cancer drugs in the NHS in Scotland. I am grateful to the Committee for the opportunity to consider the recommendations arising from the inquiry and for allowing a brief extension for the submission of this response.

This inquiry dealt with a number of complex and contentious issues, and did so in the context of the sad death of Mr Gray. The outcome of the inquiry has highlighted that much in the current system is working well and ensures that, in Scotland, all new drugs receive early consideration by the Scottish Medicines Consortium (SMC) and that NHS Boards ensure that drugs recommended by the SMC are made available on an equitable basis and in line with the clinical needs of patients. However, I remain keen to ensure where there is scope to develop and improve the current system that appropriate action is taken.

I am pleased, therefore, to submit the Scottish Government’s response, which is attached. The forthcoming Better Cancer Care Plan, the Scottish Government’s eHealth Strategy, and the forthcoming response to the recent evaluation of the Scottish Medicines Consortium (which considered how the establishment of the SMC has impacted on and engaged with its key stakeholders, and examined how SMC advice has shaped the use of medicines across Scotland) are the principal means by which the Committee’s recommendations will be addressed. In addition, specific areas of work will be commenced with a focus on the principles for decision making at local level, including exceptional prescribing and the funding of drugs; a review of information available to the public; and research on health economics methodologies.

St Andrew’s House, Regent Road, Edinburgh EH1 3DG
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I would wish to thank the Committee for its work in this area and for producing a report which will help to ensure there is appropriate access to drugs which will be of benefit in the treatment of cancer.

Best Wishes

NICOLA STURGEON
ANNEX

SCOTTISH GOVERNMENT'S RESPONSE TO PUBLIC PETITIONS COMMITTEE INQUIRY INTO THE AVAILABILITY OF NHS CANCER TREATMENT DRUGS

Defining Roles
(paragraph 43)

Recommendations

We invite the Scottish Government, in its written response to this report, to indicate:

- whether any form of monitoring is required of the roles of the national and local bodies in the drug appraisal process and what streamlining and efficiencies can be identified and introduced;

- how performance management arrangements, as referred to in its written evidence to us, would be used to address any shortcomings and when it would consider it appropriate to use such arrangements; and

- how it will provide more openness and transparency in this process, with greater patient involvement, particularly at the local level.

Scottish Government Response

NHS Quality Improvement Scotland and NHS Boards are already held to account through NHSScotland accountability and performance management arrangements. The Chair of the Scottish Medicines Consortium meets regularly and formally with the Chief Medical Officer and the Chief Pharmaceutical Officer. Accordingly, we are satisfied that the current arrangements in place at national level are robust and working well. However, these arrangements will be kept under review and where appropriate we will use the findings from existing areas of work such as the recently completed Scottish Medicines Consortium evaluation; and developments in relation to NICE and NHS QIS to identify areas for improvement.

The current arrangements, as set out in guidance, require NHS Boards to ensure that, in the planning and provision of NHS services, drugs (or their equivalents) recommended by the SMC are made available on an equitable basis and in line with clinical need. In general, these arrangements are considered to work well. Where there is evidence that a recommended drug (or its equivalent) is not being made available this would be addressed directly with the NHS Board concerned in order that appropriate action is taken where necessary.

There is a need to ensure that the 'end-to-end' process (i.e. from licensing through to exceptional prescribing panels) for the introduction of new drugs is explained in a way which is accessible and understandable, through the most appropriate media, to the general public. We will work with key stakeholders and through our existing public involvement arrangements to produce this guidance, identifying and building on existing good practice in NHS Boards. In addition the forthcoming Better Cancer
Care Plan will highlight the need to consider ways of improving the public's understanding of the role and availability of chemotherapy drugs.

Working with the Scottish Medicines Consortium, NHS Boards and their Area Drugs and Therapeutics Committees, and the Scottish Cancer Task Force, we will articulate the principles against which local decision making arrangements should operate, based on the findings of the Petitions Committee Inquiry and good practice identified at local level. NHS Boards will be asked to benchmark their processes against these principles and further develop their arrangements in line with local circumstances. This will include requirements with regard to patient and public involvement where this is appropriate. However, requirements to ensure clinical confidentiality mean that this type of participation may not always be possible. These issues are considered further under the 'Funding' heading below.

Timescale

Commence work in October 2008 with a view to completion by March 2009; and in line with the timescales set out in the workplan established by the Scottish Cancer Task Force and the response to the SMC evaluation.

Guidance
(paragraph 54)

We invite the Scottish Government, in its written response to this report, to:

- clarify how it monitors the expectation that NHS Boards and clinicians take 'full account' of initial SMC advice following its appraisal of a drug and guidance from NHS QIS in the light of a NICE Multiple Technology Appraisal; and

- investigate the apparent regional variations in the implementation of guidance, whether such variations are of concern and, if so, what action it is taking as a result.

Scottish Government Response

NHS Quality Improvement Scotland and NHS Boards are already held to account through NHSScotland accountability and performance management arrangements. The current arrangements, as set out in guidance, require NHS Boards to ensure that, in the planning and provision of NHS services, drugs (or their equivalents) recommended by the SMC are made available on an equitable basis and in line with clinical need. In general, these arrangements are considered to work well. Where there is evidence that a drug (or its equivalent) is not being made available this would be addressed directly with the NHS Board concerned in order that appropriate action is taken where necessary. The current guidance will be kept under review.

The forthcoming Better Cancer Care Plan, and the response to the recently completed evaluation by the Scottish Medicines Consortium will provide the opportunity to monitor and address inappropriate variation in the planning and provision of drug use in cancer services.
Timescale

In line with the timescales set out in the workplan established by the Scottish Cancer Task Force; and, the response to the SMC evaluation.

Data Gathering
(paragraph 60)

We invite the Scottish Government, in its written response to this report, to:

- indicate how it will take forward discussions with key health professionals and others as appropriate on the provision of a national data gathering system; clarify what data will be gathered, why, how this will be done, by whom and what purposes this data will fulfill; and indicate the timeline for taking this forward; and

- give careful consideration to any procurement or scoping work for data gathering projects and how these might be adapted, if appropriate, to capture more extensive data as highlighted in the evidence to this Committee.

Scottish Government Response

The gathering and analysis of data is fundamental for the planning and provision of NHS services. Work is already being taken forward to ensure appropriate data is gathered, analysed and used to inform decision making. For example the forthcoming Better Cancer Care Plan will describe the pilot project to develop the C-PORT system for Scotland which is used to support capacity planning for chemotherapy services. The Chemotherapy Prescribing and Administration System (CEPAS) project aims to procure and implement a specialised IT system to directly support chemotherapy prescribing within and across cancer networks. Two of the core benefits sought are to: optimise cost-effective use of chemotherapy; and provide a mechanism for the analysis of patient and treatment data. CEPAS will be developed regionally in the cancer networks and brought together nationally. Work is also underway with regard to systems to support electronic prescribing in hospitals; and the utilisation of medicines in clinical settings. The Scottish Government’s Better Cancer Care Plan, the Scottish Government’s eHealth Strategy, work being taken forward by the National Services Scotland (NSS) Medicines Utilisation Unit, and the response to the Scottish Medicines Consortium evaluation (with a focus on the feasibility and benefit of routinely monitoring uptake of SMC advice) are the principal means by which an integrated, strategic approach will support the future development of electronic prescribing, medicines management, and the planning and provision of chemotherapy services.

Timescale

Work has already commenced and will continue in line with the timescales set out in the workplan established by the Scottish Cancer Task Force; and related areas of work through the eHealth Strategy.
Quality Adjusted Life Years
(paragraph 70)

We invite the Scottish Government, in its written response to this report, to:

- indicate how it will take forward initiating research into the area of health economic methodologies, and the QALY process, and to take forward consideration of the scope of any such research with key health professionals and cancer groups and patient representative bodies.

Scottish Government Response

The Scottish Government is now participating in the Office for Strategic Coordination of Health Research (UK) (OSCHR), and through the Chief Scientist Office engaging with their methodology panel in order to pursue these issues. The Scottish academic sector has significant health economics expertise and will continue to generate proposals for future studies and research.

Timescale

Work has already commenced. Completion of particular studies and research activities will be dependent on the nature and scope of the work to be undertaken.

Availability (covering exceptional prescribing)
(paragraph 90)

We invite the Scottish Government, in its written response to this report, to indicate:

- how it will put in place the production of information that can be made available to patients setting out options and directions for the ‘exceptional prescribing’ route;

- how it will involve patient bodies and others in the preparation of this information;

- how it will develop a more participatory process for the patient and their clinician in the consideration of their ‘exceptional prescribing’ case, a process that will indicate a clear timeline for action that is no longer than two weeks;

- how it will improve communication between the NHS Board, the patient and the clinician throughout this process, including the appointment of ‘liaison officers’;

- how the process will allow for participation by the patient and their clinician in all meetings of the ‘exceptional prescribing’ panel and that the panel itself has a patient representative body member on it; and

- how it will develop a consistent approach across all NHS Boards in considering non formulary requests.
Scottish Government Response

There is a need to ensure that the 'end-to-end' process (i.e. from licensing through to exceptional prescribing panels) for the introduction of new drugs is explained in a way which is accessible and understandable, through the most appropriate media, to the general public. We will work with key stakeholders and through our existing public involvement arrangements to produce this guidance, identifying and building on existing good practice in NHS Boards. In addition the forthcoming Better Cancer Care Plan will highlight the importance of improving the public's understanding of the availability and role of chemotherapy drugs.

Working with the Scottish Medicines Consortium, NHS Boards and their Area Drugs and Therapeutics Committees, and the Scottish Cancer Task Force we will articulate the principles against which local decision making arrangements should operate, based on the findings of the Petitions Committee Inquiry and good practice identified at local level. NHS Boards will be asked to benchmark their processes against these principles and, where necessary, further develop their arrangements in line with local circumstances. In relation to exceptional prescribing arrangements consideration will be given to patient and public involvement where this is appropriate. However, requirements to ensure clinical confidentiality mean that this type of participation may not always be possible. It is also the case that some patients may not wish or, indeed, be able to participate. In terms of the length of time taken for the Exceptional Prescribing Panel to reach a decision the timescale should be determined by clinical need, for example for some patients a decision will need to be reached in a matter of days; for other patients a longer period for a decision may be appropriate. The key point is that the patient and their clinician should have a clear understanding of the timescale for a decision and that this should happen as quickly as is practicable and in line with the patient’s clinical needs.

The development of the principles underpinning local decision making processes will reflect these issues and also take account of the work of the Difficult Decisions Short Life Working Group which follows on from a workshop held in February this year where representatives from NHS Boards, Scottish Government and Scottish Universities discussed 'difficult decisions' relating both to the planning of healthcare services and the care of individual patients. The next stage of this work will be to consider principles for making difficult decisions which are transparent, accountable and robust enough to withstand scrutiny. In Scotland, our approach will focus on ensuring appropriate involvement of the public through established public engagement arrangements; patient safety; clinical and professional accountability; probity and safeguards for the NHS and its patients; and ensuring the anticipated benefits of the treatment which the NHS can offer are realised.

Timescale

Commence work in October 2008 with a view to completion by March 2009; and in line with the timescales set out in the workplan established by the Scottish Cancer Task Force and the response to the SMC evaluation.
Funding
(paragraph 101)

We invite the Scottish Government, in its written response to this report, to:

- clarify how it will take forward a review of its guidance to NHS Boards on concurrent NHS and private treatment and the policy itself.

Scottish Government Response

At the outset it is important to underline that any consideration of co-payments takes place in the context of the principles which underpin the NHS and which the Scottish Government reiterated recently along with the other UK countries. These principles are set out below:

- the NHS provides a comprehensive service, available to all;
- access to its services is based on clinical need not an individual's ability to pay;
- the NHS aspires to high standards of excellence and professionalism;
- NHS services must reflect the needs and preferences of patients, their families and their carers;
- the NHS works across organisational boundaries with other organisations in the interests of patients, communities and the wider population;
- the NHS is committed to providing the best value for taxpayers' money, making the most effective and fair use of finite resources;
- the NHS is accountable to the public, communities and patients that it serves.

The issue of co-payments is receiving considerable attention. Currently, where issues regarding co-payments arise in the NHS, NHS Boards and clinicians are required to make decisions on a case by case basis within an operating framework set out in guidance from the Chief Medical Officer and Chief Pharmaceutical Officer (see CMO(2007)3). The principal issue which has arisen in the interpretation of this guidance concerns the extent to which NHS treatment can be included or excluded from an episode of care which may comprise NHS and private elements. Current guidance (based on the NHS consultants contract) confirms that a patient cannot be treated in the private sector and the NHS at the same time for the same episode of care by the same consultant. The interpretation of episode of care seems to be the main bone of contention in determining which elements of private and NHS care can be combined and how this should be managed. The nuances of individual cases vary, making it difficult to provide a single prescriptive approach which can be applied in every situation. There cannot be a 'one size fits' all approach in determining the extent to which elements of NHS and private healthcare could be combined given the potential range of scenarios.

Consideration of co-payments reveals a complex set of issues at policy level, and at a personal level for patients. Some of these patients feel they are being denied NHS treatment and the opportunity to enhance their own care. A review of the existing guidance needs to have regard to the legal position; and further work will be necessary in order to ensure the clarity and robustness of the current framework for making decisions regarding the appropriateness of NHS care and private care being
provided for the same patient at the same time. Doing so will require engagement with NHS clinicians and managers and a wider group of stakeholders.

Context

It is important to underline that the context in which the co-payment issue arises is where the Scottish Medicines Consortium has not recommended a particular drug or a NICE Multiple Technology Appraisal endorsed by NHS QIS has not recommended a drug; and, where local processes for exceptional prescribing (including any appeals) have been exhausted. Recommendations from the SMC (and NHS QIS for MTAs) focus on groups of patients. Where an individual patient's circumstances differ from that group, existing arrangements in the NHS allow for further consideration through exceptional prescribing arrangements which focus on the patient's ability to benefit given their particular clinical situation. These panels assess the extent to which a drug could be provided and the extent to which the particular patient being considered has the ability to benefit. The overall decision pathway is set out in the Appendix to this paper and, in my view, we need to position the concurrent treatment issue in this broader process. It is worth underlining that decisions through exceptional panels are not based solely on cost; the likelihood of clinical benefit is a key element of such decisions. Where a decision is made in favour of providing a drug through the exceptional prescribing route then all the patient's care will be provided by the NHS.

NHS and Private Treatment

The NHS provides treatment free of charge at the point of access. Unless legislation allows, the NHS cannot charge patients. Patients may, however, exercise their choice to receive some or all of their care from the independent healthcare sector. There is also legislation which enables the NHS to make services and accommodation available for NHS consultants to provide private treatment on NHS premises, and to raise revenue through this route. However, this is to enable a consultant's private patient to be seen and treated in NHS premises – not as a way for NHS patients to be charged for their NHS care.

The principal issue for consideration is where, for the same element of care for their particular clinical condition, patients wish to combine their NHS care and care from the private sector. The parameters of an episode of care should be identifiable - a treatment which has a defined intervention with known endpoints; and where there are arrangements in place to deal with pre and post treatment assessment, and arrangements to deal with any complications which may arise. However, comorbidity or particularly complex diseases may mean that patients are receiving a range of treatment interventions simultaneously. In such cases the parallel treatment pathways should be clearly delineated with clear lines of clinical accountability for each element of care i.e. if complications arise it is immediately evident which clinician is responsible. All clinicians involved need to ensure they are fully cognisant with all the patient's current and planned treatment interventions. This requires good lines of communication between clinicians through agreed protocols, and explicit cross referral arrangements.
The implications of multiple and simultaneous elements of care – including those where a patient wishes to include an additional element of care on a private basis – may create a lack of clarity with regard to the parameters of an episode of care. This raises important questions relating to the extent to which the 'proximal effect' of treatment provided through co-payment arrangements is likely to compromise:

- patient safety
- clinical or professional accountability
- probity and safeguards for the NHS and for patients
- the anticipated benefits of the treatment plan which the NHS can offer

All of this suggests that decisions on co-payments or treatment need to be underpinned by (a) set of guiding principles; and (b) risk-based approach. On this basis, where a drug or treatment is not otherwise available within the NHS on the grounds of clinical and cost effectiveness, and where there are risks identified which are highly likely to compromise patient safety, clinical or professional accountability, probity and safeguards, and other elements of the patient’s NHS care, providing NHS and private treatment in combination would be unlikely to be a viable option. Where there is a lesser risk, then there may be a case for simultaneous care in the NHS and the private sector where there are clear clinical accountability and governance arrangements in place. Professional judgements need to be made in individual cases, and such judgements may be finely balanced. Assessments and judgements in relation to risk and clinical benefit are therefore part of normal, daily practice. Decision-making in relation to a patient who believes they can enhance their health through additional treatment which they exercise a choice to purchase should be seen as part of a similar framework of assessment of risk and clinical benefit.

**Next Steps**

In terms of next steps it will be necessary to establish the extent to which the current arrangements are working and whether patients who are seeking a concurrent approach are being disadvantaged i.e. denied NHS care that they are entitled to because of restrictions on the ability to combine NHS and private treatment; or advantaged i.e. obtaining an enhanced level of care not available to other NHS patients of an equivalent or greater clinical need because of their willingness to pay for additional treatment.

In the context of the wider recommendations made by the Petitions Committee the arrangements for exceptional prescribing and the management of co-payment situations need to be made more transparent and explicit. As described above, such an approach would be undertaken as part of a wider approach to provide information to the public on how the whole system of decisions about the introduction of new drugs works, including arrangements for requests for treatments not recommended for use in the NHS. This would be combined with a review of the existing basis on which Area Drugs and Therapeutics Committees and exceptional prescribing arrangements work, together with consideration for lay involvement.
The existing guidance has been in operation for over a year. Its application will be explored in conjunction with NHS Boards in order to identify areas where the guidance needs to be revised and strengthened and to identify good practice.

In conclusion, further work to review the current arrangements and guidance will need to ensure the wider interests of the majority of NHS patients are protected, while ensuring those who wish to use the independent healthcare sector for aspects of their care are able to access the NHS treatment to which they are entitled.

**Timescale**

Commence work in October 2008 with a view to completion by March 2009; and in line with the timescales set out in the workplan established by the Scottish Cancer Task Force and the response the SMC evaluation.

**Pharmaceutical Price Setting**  
(paragraphs 103-108)

We invite the Scottish Government, in its written response to this report, to:

- to carefully consider the case for initiating research into the area of health economic methodologies. An important part of that research should be how the price of a cancer treatment drug is set and the impact of the price in the QALY analysis.

**Scottish Government Response**

Pharmaceutical price setting is a reserved matter. However, the Scottish Government will seek to influence UK level discussions by reflecting the findings of the Petitions Committee’s report; and any future research in relation to QALYs.

**Timescale**

National timescales for the Pharmaceutical Price Regulation Scheme are determined at UK level. In relation to QALYs, work has already commenced. Completion of particular studies and research activities will be dependent on the nature and scope of the work to be undertaken.

**SCOTTISH GOVERNMENT**  
**3 SEPTEMBER 2008**
APPENDIX

[Attached as separate .pdf document]
SMC or NHS QIS approved or recommended?

- Yes
  - Give drug/treatment

- No
  - Refer to exceptional case panel
    - Not agreed
      - Appeal process
        - Not Successful
          - Single episode of care includes NHS/private elements
            - No
              - Allow private care as separate episode, provided no accountability/risk issues for NHS
            - Yes
              - Accountability/risk issues make private alongside NHS treatment in a single episode unacceptable
  - Successful
    - Give drug/treatment