PE1399/H

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The Scottish Government

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DELIVERING
A GAMES LEGACY FOR SCOTLAND

Our ref: PE1398/PE1399/PE1401
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Dear Anne

Thank you for your letter dated 12 October 2011 addressed to Anne Lillico/Denise McLister regarding PE1398, PE1399 and 1401. Your letter set out a number of questions that were raised at the Committee meeting held on 4 October 2011 in relation to appraisal of new medicines to treat rare conditions and the Individual Patient Treatment Request arrangements.

I am grateful to the Committee for providing the opportunity to answer these questions and the Scottish Government's response is attached.

Yours sincerely

VERONICA MOFFAT

PUBLIC PETITIONS COMMITTEE CONSIDERATION OF PE1398, PE1399 AND PE1401 - QUESTIONS ARISING FROM COMMITTEE MEETINGS TUESDAY 4 OCTOBER 2011

The Scottish Government—

- **What are your views on the issues raised in the petitions?**

To Review the SMC Mechanism and Methodology to Appraise the Value of Medicines to Treat Rare Diseases

As health is a devolved issue, decisions regarding the introduction of new medicines and treatments are taken by each of the UK countries through their own appraisal and assessment arrangements in line with established national priorities.

The arrangements in place in Scotland for appraising newly licensed medicines and treatments are through bodies such as the Scottish Medicines Consortium (SMC) and Healthcare Improvement Scotland (HIS).

The Scottish Medicines Consortium is a consortium of NHS Board Area Drugs and Therapeutics Committees (ADTCs) and considers all new medicines as soon as possible following licensing and issues advice to NHS Boards on their clinical and cost-effectiveness. The SMC was introduced to avoid duplication of new medicines assessment by individual ADTCs, to avoid geographical inequity in decision-making and to make the best use of expertise available in Scotland. The SMC operates independently from the Scottish Government and is widely acknowledged to be robust.

In assessing the relative clinical and cost-effectiveness of new medicines, the SMC requires a robust clinical and economic case to be made for the medicine in order to demonstrate value for money.

The SMC considers evidence presented to it by the pharmaceutical company responsible for manufacturing a particular medicine. After careful consideration, SMC decisions are made by a panel of experts from different fields including pharmacists, health economists, hospital doctors, general practitioners, nurse representatives, prescribing advisers, NHS Board Chief Executives, finance officers, public partners and the Association of the British Pharmaceutical Industry (ABPI) representatives. These are difficult decisions which need to weigh up a range of factors including the clinical benefits and costs.

Healthcare Improvement Scotland considers the applicability of National Institute for Health and Clinical Excellence (NICE) Multiple Technology Appraisal recommendations for the Scottish context and issues advice to NHS Boards.

Petition PE1108 was lodged on 7 January 2008 and called on the Scottish Parliament to urge the Scottish Government to consider the provision, on the NHS, of cancer treatment drugs, in particular cetuximab, to ensure equity across the NHS Boards on the appropriateness, effectiveness and availability of such treatments, The Scottish Government, in responding to Petition PE1108, took forward a package of measures to improve access to all newly licensed medicines in the NHS in Scotland. These included three separate pieces of guidance to NHS Boards to provide frameworks which:

(i) support decisions regarding the possible combination of elements of NHS and private health care;

(ii) indicate the key elements which should feature in the development of local policies for the introduction and availability of newly licensed medicines; and

(iii) NHS Boards should, as a matter of good practice, operate when dealing with requests for medicines which have not been recommended for routine use within NHSScotland.

The Petitions Committee closed Petition PE1108 at their meeting on 8 March 2011. In doing so, the Committee recognised the "many positive actions" that were being taken forward by the Scottish Government as a result of the Petition which would bring about "real improvements" across Scotland.

The Scottish Government has agreed to monitor NHS Board progress in implementing the guidance issued to NHS Boards on the introduction and availability of newly licensed medicines in the NHS in Scotland following a period of operation. Where there is evidence that NHS Boards are not complying with the guidance, the Scottish Government has committed to pursue this directly as required.

Health Economics Tool to Measure Benefits of Medicines

A QALY is a quality-adjusted life year, based on credible evidence of life years gained through clinical trials and views of the quality associated with that gain. The use of QALYs is currently the accepted method in health economics used by the SMC to compare between very different medicines and patient groups.

QALYs provide the basis for discussion within the SMC appraisal of medicines, the QALY alone does not determine the SMC decision.

The SMC published a user-friendly description of the QALY and how it is used in the SMC appraisal on their website in March 2011:
http://www.scottishmedicines.org.uk/About_SMC/Policy_Statements/A_Guide_to_Quality_Adjusted_Life_Years

Application of Modifiers in SMC Appraisal

The SMC may exercise greater flexibility in its decision-making to allow consideration of additional factors in certain circumstances. These may allow the SMC to accept a higher cost per QALY or more uncertainty in the economic case.

High Cost per QALY

The SMC has developed modifiers to be used when appraising medicines in particular categories where the cost per QALY is in excess of the normal parameters. Subject to meeting certain criteria, this allows the SMC to take into account additional factors and for the cost per QALY to be viewed flexibly with the potential to recommend a medicine notwithstanding the economic evidence provided. Where the cost per QALY is high, other factors play a role in SMC's appraisal of the medicine and may modify the final decision. These modifiers include (but are not limited to the following summary):

- evidence of a substantial improvement in life expectancy;
- evidence of a substantial improvement to quality of life;

- evidence that a sub-group of patients may derive specific or extra benefit and the medicine can be targeted at this sub-group;
- absence of other therapeutic options of proven benefit;
- possible bridging to another definitive therapy (e.g. curative surgery);
- emergence of a licensed alternative to an unlicensed therapy.

Greater Degree of Uncertainty in the Economic Case – Orphan Medicines

The SMC has also developed modifiers to be used when appraising orphan medicines. Orphan medicines are medicines used to treat or prevent life-threatening rare diseases which affect fewer than five in 10,000 people in the European Union.

The submitting manufacturer for an orphan medicine is required to make the health economic case for cost-effectiveness to the SMC in the same way as for all new medicines. In reaching a decision on whether an orphan medicine can be accepted for routine use within NHSScotland, the SMC recognises that data are very often limited due to the rarity of the condition and therefore may accept a greater level of uncertainty in the economic case. Additional factors will also be considered such as whether the drug treats a life-threatening disease; substantially increases life expectancy and/or quality of life; can reverse, rather than stabilise the condition; or bridges a gap to a "definitive" therapy.

The full list of SMC modifiers are published on the SMC website: http://www.scottishmedicines.org.uk/About_SMC/Policy_Statements/SMC_Modifiers_used_in_Appraising_New_Medicines

Individual Patient Treatment Requests (IPTRs)

The decisions of individual clinicians in relation to patient care are a matter of professional judgement. However, all NHS staff operate within the management framework of their employing organisations.

NHS Boards have arrangements for clinically-led consideration of medicines for individual patients, where the clinicians responsible believe the patient would benefit from a medicine which has not been recommended by the SMC.

The Scottish Government published a guidance framework for NHS Boards in March 2011 which they should, as a matter of good practice, operate when dealing with requests for medicines which have been appraised within their licensed indication by the SMC or Healthcare Improvement Scotland but have not been recommended for use within NHSScotland. This can be viewed via the following link: http://www.sehd.scot.nhs.uk/cmo/CMO(2011)03.pdf

- **Will you undertake a review as requested by the petitioners?**

The Scottish Government will give consideration to the extant arrangements for appraisal of medicines to treat rare diseases.

- **Will you ask the Chief Medical Officer to undertake a review of the criteria for accessing the individual patient treatment requests?**

Whilst the Scottish Government has sought to improve access to newly licensed medicines, it is important to recognise the potential for further refinements to the processes which underpin the introduction and availability of newly licensed medicines in Scotland following this period of operation.

The Chief Medical Officer and Chief Pharmaceutical Officer have been asked to review extant processes. The focus will be on ensuring the timeous consideration of SMC accepted medicines across all NHS Boards in Scotland and any associated wider Board governance procedures, including the IPTR arrangements.

- **What is your response to the suggestion by Alastair Kent that "the Scottish system is more likely to say no than yes to access to therapies for rare diseases"?**

As the Scottish Medicines Consortium operates independently from the Scottish Government, any queries relating to their decisions are for the SMC to consider.

- **The Committee was told that The Advisory Group for National Specialist Services (AGNSS) has two observers from the Scottish Government's Health Department. What consideration has the Scottish Government given to adopting a similar approach for Scotland, please give reasons?**

The national commissioning website confirms that the Advisory Group for National Specialist Services (AGNSS) is a committee that advises Health Ministers on which services should be nationally commissioned and the centres that should provide them (in England). The Group was established following the consultation, "Strengthening National Commissioning" and its role is to advise Ministers on (a) which highly specialised services, products and health technologies should be, or no longer be, nationally commissioned; (b) which centres should be designated as providers for nationally specialised commissioned services and whether to renew or withdraw the designation at the appropriate time; and (c) the annual budget for new and existing nationally commissioned specialised services and the contribution required from Primary Care Trusts (PCTs).

In Scotland, national commissioning for highly specialised services is carried out by National Services Division (NSD) of NHS National Services Scotland (NSS). New services for designation or consideration of case(s) for de-designation are considered by the National Services Advisory Group whose advice is in turn provided to Scottish Ministers for decision. These arrangements are currently under review by the National Planning Forum.

Where it is safe, sustainable and effective to do so, such services are commissioned and provided within NHSScotland. In other instances, where the incidence of the relevant disease or condition is so low that it is not practicable to commission a service in Scotland – the National Specialised Commissioning Team (NSCT) commission and provide services on a UK basis, i.e. for the whole of the population of the UK.

Where UK commissioned services are provided for residents in Scotland, these services are most often commissioned and paid for via NSD, but NHS Boards may also seek appropriate treatment and care for individual patients directly with relevant providers in England, in which case the Board concerned accepts responsibility for payment on an extra contractual basis.

AGNSS includes representatives from devolved administrations as Observers. Scotland has one such observer, Mrs Deirdre Evans, Director, National Services Division. A deputy is

allowed if she is unavailable and this is normally Dr Mike Winter, Medical Director, National Services Division.

Scottish Government Health Directorates receive the agenda and papers for each AGNSS meeting.

- **Within the context of the Pharmaceutical Price Regulation Scheme and procurement legislation what opportunities are there for the NHS in Scotland to improve the procurement of orphan drugs in order to mitigate against the high cost of these medicines and improve availability?**

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism which the Department of Health (on behalf of the UK health departments) uses to ensure that the NHS has access to good quality branded medicines at reasonable prices. The scheme seeks to achieve a balance between reasonable prices for the NHS and a fair return for the industry to enable it to research, develop and market new and improved medicines. Within the context of PPRS and procurement legislation the NHS in Scotland can improve the procurement of orphan drugs in order to mitigate against the high cost of these medicines and improve the availability by using the existing Patient Access Scheme (PAS) arrangement.

When submitting a medicine (including an orphan medicine) for consideration by the Scottish Medicines Consortium (SMC), manufacturers can propose a Patient Access Scheme in order to improve the cost-effectiveness and availability of the medicine. The Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland, reviews and advises NHS Scotland on the feasibility of proposed schemes for implementation. PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a Patient Access Scheme that has been accepted by PASAG, an implementation pack, which describes the operation of the scheme is circulated to Area Drug and Therapeutics Committees and NHS Boards together with the SMC advice.

- **Is National Procurement managing any pharmacy contracts which include orphan medicines, and if not does it have any plans to do so. In addition, does National Procurement, from its experience, believe that there could be more cost effective ways for procuring orphan medicines?"**

As far as we are aware, National Procurement is not currently managing any contracts which include orphan drugs. National Procurement is based within NHS National Services Scotland and operates independently from the Scottish Government; therefore any queries regarding their plans to consider contracting for orphan drugs and consideration of more cost-effective ways for procuring orphan drugs are matters on which they would wish to respond