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Dear Professor Richards

Consequences of Additional Private Drugs for NHS Care

We welcome this Review and hope it will lead to greater clarity about the issue of “top-ups” and more consistency and fairness in how patients who want to supplement their NHS care with additional privately-funded treatments are advised and dealt with.

Background - The Royal Pharmaceutical Society of Great Britain

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century*, the Society is working towards the de-merger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

Guidance on top-up payments

There are a number of key guidance documents on the issue of top up payments which highlight the need for clarity in this area;

- Part 1, section 1, subsection 3 of the *National Health Service Act* (2006), states that “the services so provided must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed.”¹ This section was recently used by the Parliamentary Under-Secretary of

State for Health, Ivan Lewis, as the legal basis supporting restrictions on mixing public and private funding.ⁱⁱ

- The Department of Health *Code of Conduct for Private Practice* issued in April 2003 and updated in January 2004 states that “a patient cannot be both a private and a NHS patient for the treatment of one condition during a single visit to a NHS organisation.”ⁱⁱⁱ
- The 1986 guidance *The Management of Private Practice in NHS Hospitals in England and Wales* defines an episode of care as “a judgement that must be made locally by clinicians and the local national health service, not by the Government, and so there is no reason to specify different types of episode of care. Clinicians may judge that treatments that run concurrently should be regarded as separate episodes.”^{iv}
- The Western Provident Association commissioned Nigel Giffin QC to provide a legal opinion on combining NHS and private treatment which states “I see no bar in law to a patient buying his own drugs and having them administered as part of a course of NHS treatment.”^v
- Advice issued by the Chief Medical Officer and Chief Pharmaceutical Officer to the Scottish NHS states that “there is no legislation that allows NHS Boards to require the patient to pay for all aspects of their treatment if they opt to pay for a particular drug or other treatment not currently available from the NHS.”^{vi} Yet it also states that ‘NHS consultants cannot treat a patient both as a private and as an NHS patient for the treatment of one condition during a single visit to an NHS organisation.’^{vii}
- The *Futures Debate paper on Top Ups* published by the NHS Confederation also quotes the Department of Health’s Code of Conduct document as the source of NHS rules regarding top ups. It also states that the Code was intended to advise consultants rather than hospitals, to prevent consultants from moving NHS patients into their private practices, “but has been interpreted as applying to the NHS in general.”^{viii}

The issue of top-ups is also being debated in Scotland.^{ix}

Currently, there is widespread concern that these policies are being applied inconsistently. Various media reports have stated that some consultants are currently ignoring the Government’s guidance and the Department of Health’s policies.^x There is also anecdotal evidence that some Trusts and Primary Care Trusts (PCTs) are struggling with service decisions while NICE makes its determinations. There also appear to be varying definitions of what constitutes ‘a single episode of care’ applied to different patients.

In addition the NHS Confederation has stated that “the credibility of the current strict ruling is further damaged by local PCTs reversing their decisions to refuse to fund a particular treatment following individual campaigns, by citing particular special circumstances.”^{xi} If the current policies are being implemented inconsistently then geographical inequalities will remain and public confidence in the NHS may decline.

The wider context

NHS patients mix private and publicly-funded care in many different ways and have done so for decades. This has not apparently destabilised the NHS, made citizens unwilling to pay more tax to fund the NHS, or created a general sense of unfairness about how people access it.

Pharmacy is a prime example of a public-private partnership in health: patients access prescription medicines and over-the-counter medicines via pharmacies, often at the same time and sometimes for the same medical condition. Moreover, the government has encouraged the development of multiple access routes to medicines, for instance by de-regulating some medicines (such as Simvastatin and emergency hormonal contraception) so that they can be purchased in pharmacies, while remaining accessible via GPs on prescription as well.

The government's increasing emphasis on patient choice is also relevant: the message that patients can have complete freedom of choice of any willing provider (public or private) that meets the NHS tariff price, yet cannot choose to spend their own money on additional care not available under the NHS, is a very difficult one to justify and sell to the public. The government risks sending mixed messages about its policy on choice, and could undermine its own efforts to drive up quality and outcomes by increasing choice and competition.

The NHS has not been entirely "free at the point of use" since 1952, when prescription charges were first introduced.^{xii} NHS dental care, sight tests and spectacles are subject to eligibility restrictions and/or co-payments. Other charges (e.g. for hospital car parking) can impose a substantial burden on regular users of some NHS services.^{xiii} But these charges fall into the category of co-payments rather than top-ups.

So the question arises, why is the issue of top-ups in relation to certain cancer drugs not approved for NHS use by NICE so contentious, when the numerous other examples of mixing private and publicly-funded care seem to be far less controversial? The current situation seems to be that mixing private and public care is allowed (or even encouraged in some situations – as with OTC Simvastatin) for less serious or imminently life-threatening conditions, but for patients with terminal cancer they are forbidden.

New cancer treatments

The 2007 Cancer Reform Strategy acknowledged that cancer was the leading cause of mortality in people under the age of 75 and a major cause of public concern.^{xiv}

Cancer treatments have progressed significantly in the last 20 years and new drugs are continually being researched and developed. Increasingly new drug treatments are targeted to smaller patient cohorts and specific types of cancer.

These drugs have the potential to effectively extend the life of certain individuals for a number of months. However, as these drugs are designed for a smaller number of patients, they are more expensive than current treatments.

As such these drugs may be unable to meet NICE and NHS commissioners' cost effectiveness requirements. Yet individual patients (and their clinicians) may still consider these drugs valuable and opt to top up their care by paying for them privately. Some patients who have made top up payments have then been charged for the NHS package of care they need which they had previously accessed for free.

Objections to top-up payments

There would seem to be three main grounds for objection to top-up payments:

1. Equity (fairness)
2. Pragmatic
3. Strategic.

Objections on the grounds of equity

The argument based on equity is that top-ups are unfair: why should some patients have access to drugs that others do not? The perception of unfairness is largely just that - a perception: there is a presentational problem in patients on the same NHS ward receiving different levels of care according to whether they can afford to pay privately for additional treatment. This happened before NICE was created, when different health authorities funded different treatments for patients treated in the same hospital, and is commonplace in other countries, where patients with different insurance plans are covered for different levels of care. If other patients are not actually being disadvantaged, is the issue anything more than a presentational one?

Pragmatic objections

The cases that seem to have raised the most acute issues in relation to top-ups have arisen when patients need to have an additional private treatment administered through an NHS facility in conjunction with their NHS treatment. But some patients will receive additional care in a private facility, or at home, so the perceptual and practical difficulties do not arise in those circumstances. There is certainly a justification for a charge to be made to cover the additional costs to the NHS of administering a privately-funded treatment.

Strategic objections

An argument has been made that allowing top-ups would undermine the core principles of the NHS: a two-tier service could emerge, with a minimal safety net at one level^{xv}, while the most effective treatments would only be available to those who could pay for them (we think this would be undesirable on both equity and economic efficiency grounds^{xvi}). Yet that has not happened in countries such as France which operate a predominantly publicly-funded service combined with optional top-up health insurance: the two systems seem to be able to co-exist.

There is, however, a risk that a ban on top-ups could seriously undermine the NHS: people pay taxes to fund the NHS in the expectation that it will provide the treatment they and their families need, when they need it.^{xvii} If citizens come to doubt this, they may feel the need for top-up insurance, or even complete private health insurance (for those who can afford it), and be less willing to pay large amounts of tax to fund the NHS. The government cannot provide comprehensive healthcare unless taxpayers will pay for it and vote for it. This seems to us a much more serious risk to the future of the NHS than any perceived unfairness in allowing top-ups.^{xviii}

To sum up: we consider that the arguments against top-ups are weak:

- The arguments based on equity are largely presentational
- The practical objections could be met by charging for excess costs incurred by the NHS in administering privately-funded treatments
- The strategic objection cited by opponents of top-ups is less of a threat than a loss of public confidence in the NHS's ability and willingness to provide life-saving or life-extending drugs.

For these reasons, we consider that top-ups should be allowed. However, this should not be done in isolation because the current arrangements are unsatisfactory in a number of ways.

Weaknesses of the current system

If top ups are to be allowed for cancer drugs and other expensive medicines, it would be desirable to make a number of changes to the current arrangements to help patients make informed decisions, to ensure patients know their rights (e.g. through the NHS Constitution), to

ensure that decision making is speeded up and that the number of cases where difficult decisions have to be made is minimised.

Focus of the Review

We suggest that the Review does not attempt to devise a policy on mixing private and publicly-funded care that applies to the whole of the NHS: we think this is unnecessary and would probably create more problems than it solved. As the main bone of contention seems to be about a small number of cancer drugs that have not been approved by NICE, we think the Review is right to focus on that.

A potential way forward

It has been suggested that NICE should speed up its processes, but there seems to be an impasse for some new drugs - NICE does not have enough data to make a decision on, but sufficient data cannot be generated because the drugs cannot be used for NHS patients before NICE has approved them. One way through this might be for trials^{xix} on NHS patients to be established for a limited time period e.g. three years, outside the normal rules. At the end of that period, NICE would have enough data to assess the drug on. If NICE then did not recommend the drug for NHS use, the data would also be available to patients to help them decide whether it was worth spending their own money on.^{xx}

There may also be some merit in making NICE's decision-making processes more responsive to holistic assessments of patients' needs for treatment and care, and in ensuring NICE's judgements about 'quality of life' are more reflective of patients' own perspectives, which may differ from professionals' assumptions about what constitutes an acceptable quality of life.

In parallel with such initiatives, there may be scope for adjustments in the way that pharmaceutical companies are paid for new drugs used by the NHS. Cost and risk-sharing schemes may have further potential (provided that transaction costs do not outweigh any savings^{xxi}). Fixed-price deals are also being explored, under which the government would pay a maximum price for a drug regardless of how many patients were treated.^{xxii}

Next steps

Some potential next steps include the following:

- Assess what is currently occurring in relation to top up payments for cancer patients;
- Consider how publicly-funded health systems in other countries deal with the issue of top-ups or co-payments, in particular the consequences of different models for the maintenance of a predominantly publicly-funded health system;
- Consider options for speeding up the NICE assessment process and obtaining better data on the effectiveness of drugs. This could include interim approvals or further clinical trials;
- Consider how NICE assessments could be made more holistic and better reflect the perspectives of patients e.g. in relation to assessments of 'quality of life';
- Consider the practicalities of any change in relation to pharmacy and pharmacists. Pharmacists have a key role and will need to be consulted on the implementation of any changes to ensure their practicality.

- Develop proposals for protecting patients and the public from exploitation through, for example, over-optimistic claims for the benefits of treatments.
- Provide greater clarity about patients' rights and NHS responsibilities in relation to current and future policies, and the information that healthcare professionals should provide to patients. The NHS Constitution may be one channel for this.

Interface between the Review and other relevant initiatives

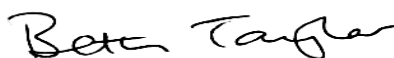
The Review should also consider how its recommendations might be integrated with several related initiatives:

- the National Cancer Research Network (established to provide the NHS with the infrastructure to support cancer clinical trials in England)
- the UK Clinical Research Collaboration (UKCRC)^{xxiii}
- *Best Research for Best Health*^{xxiv}
- the NHS Constitution.^{xxv}
- the *Ministerial Industry Strategy Group: Long-term Leadership Strategy*^{xxvi}, which proposed that "the UK should lead the world in the development and delivery of long-term innovations in medicine that aim to maximise patient well-being, at an affordable cost to society."^{xxvii} MISG also maintained that "there is little engagement between industry and NICE during development of a product and the dialogue with MHRA starts relatively late."^{xxviii} An update on the implementation of MISG's recommendations is due by the end of 2008.^{xxix}

We hope these views are of use to the Review and look forward to hearing the outcome.

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Yours sincerely,



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ⁱⁱⁱ Department of Health (2004). *Code of Conduct for Private Practice Recommended Standards of Practice for NHS Consultants*, p4 para 2.13

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^v Giffin, N (12 October 2006) *National Health Service Provision of High Cost Treatments Legal Opinion*, Western Provident Association, p11 <http://www.wpa.org.uk/legalopinion/index.html#>

^{vi} Dr Burns, H & Prof Scott, B, (5 February 2007). *Patients Receiving Concurrent Treatment from NHS and Private Providers*, Scottish Executive Health Department

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^{viii} The NHS Confederation (June 2008). *Topping Up: Should it be allowed in the NHS?*, Futures Debate Paper 4, p2 www.debatepapers.org.uk

^{ix} The Scottish Parliament's 2008 Public Petitions Committee Report *Availability on the NHS of cancer drug treatments*^{ix} considered a wide range of issues relating to the section of drugs for use within NHS Scotland. The report raised a number of concerns about the need for greater clarity in guidance and advice, information for patients and decision making processes. The Scottish Government will be responding to its recommendations in due course. The Scottish Government is also to shortly announce following consultation on *Better Cancer Care*^{ix}, its new cancer strategy.

^x 'Focus'. The Sunday Times, 8 June 2008 p12

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^{xv} echoing Richard Titmuss's comment that "A service for the poor would be a poor service" (Dean M (2000) *Rationing gets official seal of approval from UK Health Secretary*. *Lancet* 355: 49, January 1.)

^{xvi} Farrington-Douglas J & Coelho MC (2008) *Private spending on healthcare*. IPPR, p. 45.

^{xvii} Stevens – add ref

^{xviii} Polls suggest the majority of the public do not oppose top-ups or see them as unfair or against the NHS's founding principles: a YouGov poll of 1,800 people for the Sunday Times found 89% thought people who buy additional cancer drugs should continue to get free NHS treatment, and only 5% thought co-payments would create a two-tier NHS. Support for top-ups had "strong backing across the social spectrum and supporters of all three main parties"(Sunday Times, 15 June 2008, p. 5).

^{xix} In effect Phase IV clinical trials

^{xx} The Scottish Public Petitions Committee Report suggested a system whereby "on the recommendation of the clinician, the NHS board agrees to fund an agreed initial 'trial' of the drug through a set number of treatments to generate initial and early feedback from the patient and, importantly the clinician, on whether the drug is proving to be clinically effective." (Public Petitions Committee 18 June 2008. 3rd Report: *Availability on the NHS of cancer treatment drugs*, Scottish Parliament, para 99 <http://www.scottish.parliament.uk/s3/committees/petitions/reports-08/pur08-03.htm>)

^{xxi} Thompson D (11 March 2008). Position Statement on 'risk sharing' schemes. British Oncology Pharmacy Association (BOPA), p20 para 4 www.bopawebsite.org

^{xxii} GSK seeks fixed-price deal with NHS. *Financial Times*, 4 August 2008.

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