REVIEW OF THE PROPOSED ARRANGEMENTS FOR THE SUPPLY OF GENERIC MEDICINES IN NORTHERN IRELAND

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*This review was commissioned by the Pharmaceuticals Contractors Committee of Northern Ireland. All views in this paper are those of the authors and should not be held as stating or reflecting those of the above organisation, or any organisations with which the authors are affiliated

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EXECUTIVE SUMMARY AND KEY POINTS

The Department of Health, Social Services and Public Safety in Northern Ireland (hereafter Department of Health, or DoH) has proposed the introduction of a number of measures relating to the prescribing and dispensing of generic medicines in Northern Ireland. A central element of the programme is the introduction of regional competitive tendering exercises for a range of generic and branded generic products prescribed in both secondary care and primary care.

This Review has three principal aims:

1. first, to consider whether the process adopted in relation to the introduction of the proposed arrangements is consistent with current UK and EU guidelines in respect of the introduction of new policy measures, and more generally, with good public authority practice;

2. second, to examine and assess the robustness of the analysis and supporting evidence and materials presented by the Department of Health, Social Services and Public Safety (Northern Ireland) concerning the estimation of the potential impacts and effects of the introduction of the proposed new arrangements;

3. third, to assess and comment on the likelihood that the proposed use of central tendering for generic medicines supplied to the primary care sector is likely to have the consequences intended by the DoH.

On the basis of our review of the proposals, we have substantial reservations regarding the process by which the new arrangements have been developed. Serious concerns about the scope and adequacy of the consultation process have been expressed by many stakeholders, not just one or two, and those concerns appear to be well justified on the evidence available.

Associated with lack of proper consultation processes has been the relatively poor quality of information and analysis provided to stakeholders regarding how any new arrangements might be expected to operate in practice. Responses to stakeholder queries, including crucially from those suppliers of generics medicines who were or are potential participants in the tenders, have been characterised by brevity and opacity.

The general approach taken by the DoH – which might be characterised as ‘leap before you look’ – has been to leave many, highly significant implementation issues to be resolved ‘later’. This is at odds with best practice in policy development, which requires that the impacts of policy initiatives (which often depend heavily on implementation details), be fully thought through *before* those policies are adopted.

It is also at odds with what is known about the performance characteristics of competitive tendering and auctioning processes: outcomes can be highly sensitive to the fine detail of the tender rules. Even in principle, it is impossible to be confident about the consequences of a process whose detailed rules are undefined, particularly when there is so much evidence of the sensitivity of outcomes to rule specification.

In our review of relevant documentary materials, we were unable to identify any clearly defined 'problem' in the supply of generic medicines to which the proposed new central tendering system for generic medicines in the primary care sector might be considered a reasonable solution. Subsequent discussions indicate that concerns about possible patient confusion and failure to take prescribed drugs associated with a lack of standardisation within the health system may have been a major factor in developing the proposals; but how such perceived 'concordance' problems interact with other concerns that have been expressed by the DoH – such as the level of generic prescribing in NI and the magnitude of the drugs bill in NI – appears to be entirely unclear.

In the event, we could find no clear analysis or assessment of links between patient outcomes and lack of standardisation in NI or other parts of the UK. Since clear and precise identification of the perceived problem is recognised to be the starting point for effective impact assessments, in this case the evaluation process appears to have got off to a bad start.

If, contrary to our perception of the emphasis on 'concordance', the proposed central tendering arrangements for primary care generics are being introduced to address a general concern about the relatively low level of generic use in Northern Ireland, we would have expected to see reasoning or evidence showing how the changes would affect that level, particularly given that England exhibits a combination of high generic usage and *decentralised* medicines procurement, quite unlike what is being proposed. No such reasoning or evidence appears to be available.

Irrespective of the problem to be addressed, we would have expected to see an evaluation of alternative options for addressing them. If 'concordance' and/or generic prescribing levels are considered to be serious issues, there are many alternative ways in which they can (and indeed have been) addressed, which are much more directly targeted on these problems than central tendering arrangements for medicines procurement. However, the proposed central tendering arrangements appear to have been the only serious option presented by the DoH. This is inconsistent with UK, EU and OECD policy guidance on procedures for assessing the impacts of new policy proposals.

Whereas all stakeholders appear to agree that the DoH proposals could have far reaching consequences for community pharmacy, no subsequent assessment of these potential consequences, or of possible measures that might be adopted to mitigate those of the potential consequences that are harmful, has been undertaken. The relevant issues have been parked in the

'to be considered later' basket. Given the significance of community pharmacy for consumers in the primary care sector, and given the general, EU-wide public policy position on small and medium size business enterprises (of which there are many in pharmacy), the neglect of these potential impacts appears both unreasonable and irrational.

Similarly, potential effects on competition in the NI market for generic medicines have been ignored. Given that the *status quo* is characterised by a competitive generics market, with many buyers and sellers (or potential sellers), the introduction of central tendering is, as a simple matter of fact, a move toward a more monopolistic price determination process, in which prices can be expected to be much more influenced than now by DoH skills, DoH incentives, and DoH discretions. The approach, based upon a implied preference for monopsony (a single, monopolistic buyer) over competitive price determination, appears to us to run directly contrary to the guiding principles of EU competition law.

Notwithstanding both the existence of some spectacular failures among government procurement initiatives and the manifest existence of potential risks to, among other things:

- security and continuity of supply (arising, for example, from reduced diversity in supply sources and administrative errors),
- prices and quality of service, and
- the coverage of community pharmacy.

We have not been able to find, in the documentary evidence, any substantive risk assessment of the proposals. Given the importance of medicines to the community as a whole, and to vulnerable groups such as the very elderly in particular, this seems to us to be a reckless way in which to proceed.

1 INTRODUCTION AND BACKGROUND

The Department of Health, Social Services and Public Safety in Northern Ireland (hereafter Department of Health, or DoH) has proposed the introduction of a number of measures relating to the prescribing and dispensing of generic medicines in Northern Ireland. The Department has stated that:

> *The increased use of generic medicines is a key policy within the Department's Pharmaceutical Clinical Effectiveness programme. This programme promotes quality and safety improvements in medicines management arrangements which in addition to securing health gains have the potential to realise significant cash releasing efficiencies.*[1]

A central element of the programme referred to is the introduction of regional competitive tendering exercises for a range of generic and branded generic products prescribed in both secondary care and primary care. According to the DoH one purpose of introducing the competitive tendering initiative is to:

> *aim to standardise a range of generic products (including branded generics) between the primary and secondary healthcare sectors in order to ensure that patients' generic medicines are of a uniform presentation thereby optimising their confidence and concordance with these medicines.* [2]

We understand that the first stages of the competitive tendering exercise will follow the so-called 'STEPS methodology' for procurement of generic medicines. In a nutshell, the approach comprises three distinct stages:

- first, generic medicine suppliers are required to satisfy certain pre-qualification criteria , and only those which pass this stage are allowed to bid in the second stage of the tender;
- second, a clinical and safety evaluation of possible generic products that will comprise the tender list of products is undertaken, subject to review by an expert panel;
- finally, a budgetary impact assessment will be undertaken for each generic product to determine whether it will be included on the final list put to tender.

The applications for participation in the restricted tender process were issued in March 2008, and successful generic companies were invited to submit

[1] Letter of 23 June 2008 from Dr Mark Timoney to a range of recipients.
[2] ibid.

tenders by the middle of July 2008. The contracts for the primary care sector are intended to commence on 1 April 2009.

1.1 The general objectives and context of the new measures

At a very general level, the desirability of policy efforts directed toward making more effective use of generic medicines in Northern Ireland appears to be uncontroversial. Similar efforts are being made in many jurisdictions, and none of the documentary material that we have seen indicates other than support from relevant stakeholders, including suppliers of medicines and pharmacists. And although there is a view that Northern Ireland lags behind England, Scotland and Wales in this area – a view that we have not been asked to assess, and which, when all relevant differences have been taken into account, may or may not be correct – the jurisdiction cannot be regarded as a laggard when assessed on a pan European basis.

That said, it is often a long journey from consensual good intentions to the implementation of effective public policies, which depend upon getting the detail right. Steps along the way include ensuring that the case for the eventually favoured option (relative to alternative ways of proceeding) is well reasoned and supported by factual evidence – requirements that are increasingly being imposed on public authorities by the courts at both EU and Member State level. Early parts of the policy development exercise include assessing whether or not potential policies are well targeted at clearly identified deficiencies in existing prescribing/dispensing practices; an aspect of the process that might be considered to be particularly important in the current context given what has just been said about NI not being a laggard in this area by European standards. Later parts of the exercise include ensuring that all relevant effects of proposed measures – whether those effects take the form of benefits or of harm/costs – are fully taken into account, not just what might be termed the immediate, direct effects.

1.2 Structure of the review and the materials examined

Given these general opening points, this Review is divided into four, further sections, as follows.

- Section 2 outlines the purpose of the review, and identifies the key issues to be addressed in what follows – issues that relate both to the process by which the new measures have been introduced and to the potential outcomes that might be expected to arise from the implementation of the specific measures (i.e. the substantive effects of the measures).

- Section 3 examines the principal substantive issues associated with the introduction of the competitive tendering arrangements, drawing on the very wide experience of public sector tendering that is now available.

- Section 4 focuses on the aspect of the proposed new arrangements that appears to be particularly controversial, namely the introduction of central tendering for generic medicines for the primary care sector.

- Section 5 summarises our overall conclusions and their implications for the way forward in relation to medicines procurement in NI.

A range of materials was examined in the course of this review, including:

- Various presentations made by Department of Health staff, including the following presentations on the Department's website: *Pharmaceutical Procurement - Generic Medicines; Briefing on Generic Medicines Tender for Primary and Secondary Care Sectors in Northern Ireland; Second briefing on Generic Medicines Tender for Primary and Secondary Care Sectors in Northern Ireland; Electronic Tendering and Next Steps in the Process; Questions and Answers to first briefing session* and *Questions – 10 July 2008 – Generics Tender.*

- Publicly available correspondence relating to the proposed arrangements between bodies such as the ABPI, the BGMA, the PCCNI and the BAPW and the Department of Health.

- The Pharmaceutical Cost Inquiry 2006 published by the Joint Department of Health, Social Services and Public Safety/Pharmaceutical Contractors' Committee.

- A study commissioned by the Department of Health and prepared by Professor John Appleby of August 2005 titled: *Independent Review of Health and Social Care Services in Northern Ireland*.

- Two reports commissioned by the Department of Health and produced by Social & Market Research titled *Public Attitudes to Health and Social Services in Northern Ireland (2005)* and *Public Attitudes to Health and Social Services in Northern Ireland (2006)* which focused on public attitudes to various aspects of primary and health and social care services, including pharmacy services.

- A market research study commissioned by the Department of Health to identify the nature, extent and experience of the public's use of community pharmacies. The research was undertaken by Pricewaterhouse Coopers in 2000 and is titled: *Community Pharmacy Activity Survey*.

- Various consultation papers, policy documents and studies published by the Department of Health in England as part of its fundamental review of the generics drug market in 2001.

- A report by the Auditor General titled *The Procurement of Primary Care Medicines* of March 2003.

- A press release from TEVA UK Limited titled *Teva declines to tender for NI contract* of 29 July 2008, as well as an open letter from John Beighton (Managing Director) of Teva to the Minister for Health, Social Services and Public Safety.

In addition, we have had regard to more general materials on how to approach policy assessments produced by the Better Regulation Executive of the UK Department for Business, Enterprise and Regulatory Reform: as well as guidance provided by the European Commission, by the Government of the RoI, and by other bodies such as the OECD. Notwithstanding some minor variations, there is a high degree of consistency in these materials about how policy assessments should be undertaken, and we rely heavily in what follows on the common principles that have been established.

As part of this review we also conducted a series of meetings. This included meeting with members of the Pharmaceutical Contractors Committee (NI), as well as a meeting with civil servants at the Department of Health, Social Services and Public Safety to discuss the competitive tendering arrangements and how they are perceived to relate to the Department's objectives.

2 ISSUES TO BE ADDRESSED

Our review of the proposed new arrangements for the supply of generic medicines in Northern Ireland has had three principal aims:

- first, to consider whether the process adopted in relation to the introduction of the proposed arrangements is consistent with current UK and EU guidelines in respect of the introduction of new policy measures, and more generally, with good public authority practice;

- second, to examine and assess the robustness of the analysis and supporting evidence and materials presented by the DoH concerning the estimation of the potential impacts and effects of the introduction of the proposed new arrangements;

- third, on the basis of this review of both process and underlying analysis, to assess and comment on the likelihood that the proposed use of central tendering for generic medicines supplied to the primary care sector is likely to result in what the DoH believes will be the expected outcomes in practice.

In particular, we have kept in mind throughout what we believe is a central, overarching question:

Are the proposed arrangements for the supply of generic medicines in Northern Ireland a reasonable policy outcome/decision that was arrived at by way of a reasonably conducted policy assessment process?

In our view, the two aspects of assessment corresponding to the two parts of this question – concerned respectively with (a) substantive outcomes/decisions and (b) the policy development process – are, in the normal course of things, closely interlinked.

While it can be expected, in nearly all decision making processes involving complex issues, that there will be scope for reasonable disagreements about the relative merits of alternative policies/decisions, it is clear that the 'margins of discretion' afforded to public authorities in resolving such disagreements are bounded. Consideration of Court decisions concerning the unreasonable exercise of executive authority suggests that there is a positive, albeit not exact, correlation between failures of process and failures of substantive decision making. Poor processes and procedures are more likely to be associated with inferior/unreasonable decisions.

Evaluation of each of the two aspects of decision making – outcomes/decisions and processes/procedures – is therefore potentially informative about the likely reasonableness of the other aspect.

We therefore begin by considering a number of matters relating to the process through which the proposed new arrangements for central tendering were introduced, particularly in relation to the scope and extent of consultation with interested parties, and to the supporting analysis regarding the proposed arrangements that was put into the public domain.

We then turn to consideration of what, in our view, are the main substantive issues that emerge from a review of the relevant materials. In particular, we examine:

- 'the problem' which the proposed measures are intended to address;
- the extent of any assessment of alternative options;
- the assessment of impacts, including competitive and other impacts; and
- the consideration given to possible risks or unintended consequences associated with the new policy measures.

Finally, we examine perhaps the most controversial element of the proposed arrangements – the proposed introduction of central tendering for the procurement of generic medicines for use in the primary care sector – and consider, at a broader level, the suitability of such a mechanism in the context of the procurement of generic medicines more generally.

3 MATTERS RELATING TO PROCESS

The purpose of this section is to look beyond the specific detail of the proposed generic supply arrangements in Northern Ireland, so as to examine at a more general level the main issues associated with the process by which the policy initiatives were developed. The procedural issues discussed are those that have emerged from our review of the relevant materials, as well as discussion with certain key stakeholders. As noted above, we believe that there is generally a significant correlation between the outcomes/decisions that emerge from a particular process and the key elements and features of the policy development process itself.

In considering the process surrounding the development of the policy initiatives relating to the supply of generic medicines in Northern Ireland we have examined both UK and EU government guidelines on policy development.

3.1 Consultation

The recognition of the critical importance of consultation to the policy process

The requirement to properly consult with affected stakeholders in the development of policy initiatives is seen as the cornerstone of good policy making. This is recognised not only in UK and EU policy process guidelines, but also in a great majority of OECD countries.

The OECD notes that the opportunity for interested parties to present their views is an essential element in regulatory decision-making, noting that:

> *Regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from interested parties such as affected businesses and trade unions, other interest groups, or other levels of government.*[3]

In the UK, the importance of effective and proper consultation in the policy development process is reflected in the Cabinet Office/Better Regulation Executive *Code of Practice on Consultation*.[4] The Cabinet Office/BRE Code of Practice document sets out 'six consultation criteria' that must be

[3] OECD 'The OECD Reference Checklist for Regulatory Decision-Making', page 1.

[4] An indicator of the perceived importance of consultation to the policy process is the fact that the foreword for the document is written by the then Prime Minister Tony Blair who begins by noting that: *"Effective consultation is a key part of the policy-making process. People's views can help shape policy developments and set the agenda for better public services".* Cabinet Office/BRE 'Code of Practice on Consultation' January 2004, page 3.

reproduced within all consultation documents by government departments.[5] These include:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.

2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.

3. Ensure that your consultation is clear, concise and widely accessible.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.

5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The importance of effective consultation to the policy development process is also recognised at the European level. The European Commission, for example, has noted that *'Public consultation contributes to regulatory quality and transparency and increases the involvement of stakeholders and the public at large in the policy-making process.'*[6] To this end, the Commission adopted a set of 'General principles and minimum standards for consultation of interested parties' in 2002, which are intended to ensure wider and more open consultation with better information and effective participation and dialogue.[7]

The minimum standards include:

- All communications relating to consultation should be clear and concise, and should include all necessary information to facilitate responses.

- When defining the target group(s) in a consultation process, the Commission should ensure that relevant parties have an opportunity to express their opinions.

[5] The Code applies to "all UK public consultations by government departments and agencies, including consultations on EU directives. UK non-departmental public bodies and local authorities are encouraged to follow this code. Devolved Administrations are free to adopt this code, but it does not apply to consultation documents issued by them unless they do so."

[6] European Commission Directorate General of Enterprise and Industry 'Consultations' available at: <http://ec.europa.eu/enterprise/regulation/better_regulation/consultations_en.htm>

[7] European Commission ''Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission' (COM(2002)704 final) on 11 December 2002.

- The Commission should ensure adequate awareness-raising publicity and adapt its communication channels to meet the needs of all target audiences.

- Without excluding other communication tools, open public consultations should be published on the Internet and announced at the "single access point".

- The Commission should provide sufficient time for planning and responses to invitations and written contributions. The Commission should strive to allow at least 8 weeks for reception of responses to written public consultations and 20 working days notice for meetings.

- Receipt of contributions should be acknowledged. Results of open public consultation should be displayed on websites linked to the single access point on the Internet.

The key point is that requirements as to the need for, and form of, consultation accompanying new policy initiatives are no longer seen as an area of wide discretion for government departments under UK and EU guidelines. Strict guidelines and consultation codes exist which specify both the need for proper consultation to be undertaken, and the manner in which consultation is conducted.[8]

Underlying rationales

Before proceeding, it may be useful to consider why consultation processes are considered so important in policy making. We believe that there are two principal reasons:

- Consultation is itself an important characteristic of the responsible exercise of power. Public authorities nowadays exercise powers that can have wide ranging, and often non transparent effects, on the public. In such circumstances, good governance requires that public officials pay appropriate attention to determining who will likely be affected, and in what ways and by how much, by any measures in contemplation. It also requires that the public be informed of measures in contemplation, and of their potential impacts, in order that their views can be expressed.

- Consultation processes lead to the discovery of new, relevant information; which can be of relevance to the decision to be taken. Even when public officials make 'best endeavours' attempts to assess the consequences of measures in contemplation for groups of stakeholders and for individual members of the public, their initial information is necessarily limited. By setting out clearly what might decided, and by providing initial assessments of what might be

[8] More pragmatically, from a Departmental/Agency perspective, deficiencies in consultation process can put Departments' at risk of judicial review.

expected from the relevant decisions, consultation processes can establish public discourses that enhance the information available to public authorities.

We make these points because, although the Devolved Administrations are free to adopt or not to adopt the UK *Code of Practice on Consultation* (see footnote 3 above), we do not think that any such opt-out from *a specific and detailed code*, implies that the principles underlying that code can be ignored. Indeed, it is difficult to conceive that any modern European public authority would seek to deny the role of consultation in (a) impeding or preventing the irresponsible or abusive exercise of power and (b) discovering and enhancing the amount of relevant information available to public sector decision makers.

The consultation process for the proposed supply of generic medicines

It is against this backdrop that we have considered the consultation process surrounding the new arrangements for the supply of generic medicines in Northern Ireland. It is immediately clear to us from a review of the relevant materials, and from discussions with key stakeholders, that the consultation process in relation to the new arrangements has fallen well short of current UK and EC guidelines best practice, and has been inconsistent with Guidelines cited above.

The Department of Health's approach to its responsibilities to consult on the proposed arrangements can be illustrated by its response to a question posed in the May *Question and Answer* session for stakeholders. Asked about the extent and type of consultation that has been undertaken with community pharmacy the Department of Health offered the following response:

> *The Pharmacy Contractors Committee (PCC), the organisation responsible for the negotiation of community pharmacy contract arrangements including those related to remuneration and reimbursement, have been **advised** about the scope of the initiative.* [Emphasis added]

This can be contrasted with the response of the Department of Health in England when considering similar fundamental changes to its generic supply and dispensing arrangements. The Department of Health in England explicitly recognised the importance of taking account of the views of pharmacists, noting that:

> *The proposals are also likely to have an impact on community pharmacy contractors. The Government is committed to maintaining good access to community pharmacy and to developing pharmacy in line with the aims set out in Pharmacy in the Future. We will take account of the views of the pharmacy*

profession in reaching decisions about the way forward for the longer term.[9]

We note that serious concerns about the scope and adequacy of the consultation process in Northern Ireland have been expressed by key stakeholders at all stages of the generic medicines supply and distribution chain. For example, concerns have been expressed by branded medicine manufactures, generic manufacturers, wholesale companies, and pharmacists:

> *The ABPI NHS Supply Chain group is very concerned, along with other key stakeholders, regarding the lack of consultation with stakeholders before the posting of the tender documentation. Prior consultation may have led to an earlier dialogue where concerns could have been shared and constructive alternatives considered.* (Letter from the Association of the British Pharmaceutical Industry to Minister McGimpsey, 18 June 2008)

> *There was insufficient consultation with stakeholders ahead of the release of the tender documents leading to confusion and requirements that cannot be met.* (Letter from British Generic Manufacturers Association to Department of Health of 4 July 2008)

> *In principle, if the process of consultation had allowed all stakeholders to fully consider the implications of the new scheme and engage properly and iteratively with your officials, then we do believe that this letter might not be necessary.* (Letter from British Association of Pharmaceutical Wholesalers to Minister McGimpsey, 24 June 2008)

> *We believe this proposal is misguided and ill-conceived and, worse still, officials seem intent on railroading it through with no regard for our legitimate concerns or for the risks to the supply chain that it poses. Contrary to the impression that has been given, the PCC has not at any stage been consulted on this proposal by the Department. We find that only disappointing but insulting. Does the Department believe that the views of pharmacists and their representative body do not matter?* (Press Release from Pharmaceutical Contractors Committee (NI) Ltd, 17 June 2008)

The consensus of views is significant since, in the normal course of events, it is not to be expected that these various groups would have an alignment of perspectives and interests in relation to any particular and specific set of proposals. What is good for one group is often not the same as what is good for another group, yet it appears to be almost universally maintained by stakeholders that there has been insufficient consultation with them prior to the introduction of the proposed new arrangements for the supply of generic medicines.

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[9] Department of Health "Options for the Future Supply and Reimbursement of Generic Medicines for the NHS: A Discussion Paper" July 2001, page 38.

Particularly given that DoH concerns relating to a perceived lack of concordance/ standardisation appear to have been a principal driver for developing the central tendering proposals (see discussion in section 4), it is noteworthy that, according to our understanding of matters, there has been very limited consultation between the DoH and patients or patient advisory bodies as to the likely impacts of these reforms.

Perhaps the single most damning indictment of the DoH's consultation process was the decision, announced on 29 July 2008 by Teva UK Ltd, the largest generic manufacturer in the UK, that the Company would not be submitting a bid in the primary care tender process. In its press release, Teva indicated that, whilst it applauded the DoH's underlying motives, the Invitation to Tender (ITT) was "flawed", that not enough information had been made available, and that "it was impossible to tender accurately."

This is an extraordinary outcome, and appears to be a direct consequence of inadequate consultation, particularly with pharmacists (Teva specifically cited the lack of information concerning how the proposals would affect pharmacy). One of the purposes of consultation is that all parties involved should be able to acquire better information, and it is difficult to conclude other than that the DoH should have known that the information that it was providing was inadequate.

3.2 The absence of supporting analysis of impacts

The effect of the absence of proper consultation in respect of the proposed arrangements appears to have been amplified by the poor quality of analysis provided to stakeholders regarding how the arrangements will operate in practice. In particular, in the materials supplied to us we have been unable to identify any analysis which assesses the potential impacts of the proposed new arrangements on different stakeholder groups, and on the supply chain in general.

The only focused material we have seen which provides any insight into how the proposed arrangements will operate in practice – and the potential impacts – are the responses to the *Question and Answer* sessions held in May and July 2008. The brevity and opacity of responses in those documents appear to be us to be well short of the level of detail and of the clarity required to address the various detailed, and sometimes complex, questions raised by participants at these events. Either the DoH withheld information in these responses or, as we suspect is much more likely, the central tendering proposals were so far from having been thought through that detailed and clear answers were impossible.

To give an example from the May session, in response to questioning on the important issue of the interaction between awards for supply made in the primary sector and secondary sector the following 'holding' response is given:

	Question	Response
52	Is the clear intention when awarding the Primary Care tender to extend the existing award made in Secondary Care (which would normally be one supplier per presentation) over to Primary Care or will the award criteria be different? Would there, for instance, be products where the Primary Care awards are to more than one supplier and, possibly, not to the original contractor for the Secondary Care tender?	*It is anticipated that a decision will be reached to promote uniformity in both primary and secondary care sectors.*

When asked a series of questions relating to the possibility of generic medicines being purchased outside of the contract awards in the first briefing session, the responses given are equally vague and incomplete:

	Question	Response
59	A significant minority of the Community Pharmacy market in Northern Ireland is supplied by the so-called short-liners, who will buy and sell products, irrespective of the intended contract awards. What mechanisms are there in place to prevent a non-contract generic medicine being sold and dispensed via this method?	*Robust contract monitoring arrangements will be implemented and reviewed by a contract monitoring group established to monitor and assess performance.*

	Question	Response
80	What steps will be put in place to prevent off-contract purchasing?	*Robust contract monitoring arrangements will be implemented and reviewed by a contract monitoring group established to monitor and assess performance.*

A similarly ambiguous response is offered in the second July briefing session:

	Name	Company	Question	Answer
12	Mike Kappler	Dexcel Pharma	If a manufacturer comes and offers lower price, can community pharmacists buy off tender?	The contract uptake will be monitored. The pharmacist will be required to procure from the contract.

It appears that, in response to a large number of questions of detail, the Department of Health's approach has been to defer the relevant matters until *after* the implementation of the new arrangements. This includes matters of significant importance such as: how contract awards will be 'split' among

different suppliers; the interaction between award contract prices and the generic drug tariffs; how retail pharmacies will access the contracted lines; and the proposed method for reimbursement of pharmacists in the event that they do not purchase the correct line. For example:

	Question	***Response***
29	I wonder if you can tell me how the volume will be spit for 'shared awards'. Will a list of specified suppliers be provided to retail/hospital pharmacists giving them the choice of whom to purchase from, or will the purchasing points be spit into regions with each region being given to a specific supplier? Obviously, from a supply point of view the latter would be preferable as it is impossible to forecast if we are unsure as to expected volume.	*Such implementation issues will be finalised after the outcome of the tender is known.*
55	If the Drug Tariff for the generic medicines is to be calculated on the basis of the awarded contract prices, for say 2 or 3 suppliers, what happens if the awarded prices are different ?	*Such implementation issues will be finalised after the outcome of the tender is known*
76	If the final agreed contract prices are going to set the Drug Tariff will it be on a fixed margin basis? What will be the agreed margin?	*Such implementation issues will be finalised after the outcome of the tender is known*
82	How will retail pharmacies access the contracted lines? Must they be available via local wholesalers? Would we have to supply wholesale at the contract prices? Who then pays the distribution costs?	*Distribution costs and the ability to meet contract distribution will be assessed at 2nd stage*
93	If pharmacists do not purchase the correct generic how will they be reimbursed	*The drug tariff will be amended in NI in tandem with this initiative.*
104	Given fluctuations in Generic prices throughout the UK, how will the contract be enforced?	*New Drug Tariff arrangements will be put in place*

This approach continued to be adopted in the second briefing session, in July, for example, in relation to how distribution costs will incorporated into the process:

	Name	**Company**	**Question**	**Answer**
6	Kim Innes	Teva	The process may be flawed if suppliers are expected to include a distribution charge. As a manufacturer, we may have to test the market for distribution costs. This would be difficult to benchmark and would take some time to achieve.	Concerns noted. Concerns noted.

7	Michael Cann	Actavis UK Ltd	If 1 price incorporates the distribution cost instead of seeking a distribution cost after the product cost, this could lead to problems with competition and could exclude small suppliers. (OFT study in Distribution) This may be in breach of competition law.	Noted

The release of such limited analysis and information into the public domain prior to such a fundamental change being introduced reflects poor policy processes. It suggests to us that either the Department of Health has not undertaken sufficient analysis of the possible consequences of the introduction of the new procurement arrangements, or, alternatively, that such analysis has been undertaken but is not being released to key stakeholders. In either event, it is clear that such an approach falls well short of current UK and EU practice.

3.3 Associated risks that are introduced

There are a number of well-recognised risks that tend to be associated with failures adequately to consult with key stakeholders about proposed policy initiatives, and, more generally, with failures properly to assess the possible impacts of the initiatives on stakeholders. The common theme is the potential harm caused by the introduction of avoidable uncertainties, and the specific effects include:

- confusion as to the policy objectives being pursued and the underlying problem being addressed;
- uncertainty regarding how current practices will be affected by the new policy measures;
- reduced incentives for investment and innovation in light of policy uncertainty;
- concerns about future security of supply under new arrangements; and
- a failure to appreciate why the change is being introduced, and therefore to act in ways which might facilitate or promote the overarching objective of the policy initiative.

From the documentation that we have read, a number of these risks have been identified for the DoH by one or other of the stakeholder groups, including in particular the possibility of confusion as to how the tender will operate, and concerns that the security of supply of generics could be adversely affected by the introduction of the new arrangements.

More specifically, we note that a failure to properly consult on or to consider the possible impacts of policy initiatives *before* introducing them runs contrary to the principles underlying various Better Regulation initiatives being pursued within the UK and the EU. From this perspective, the responses provided in the May *Question and Answer* session to rather fundamental questions about key characteristics of the proposed regime – *Such implementation issues will be finalised after the outcome of the tender is known* – is wholly unsatisfactory.

The answers to the relevant questions are material for determining the likely effectiveness of the proposed arrangements, and in particular their effectiveness relative to alternative policy options that might be adopted. For this reason, public policy guidelines increasingly seek to ensure that public officials systematically 'think through' and compare the advantages and disadvantages of different policy options, *before* they become attached to any of the various possibilities. Although the processes for the introduction of new policies vary across government departments and authorities, a common high-level objective is to introduce 'evidence-based' policy making by requiring that the potential economic, social and environmental impacts of proposed regulations be examined.[10] This focus on evidence based policy making does not appear to have featured at all in the NI process, at least in relation to material that has been put before stakeholders.

[10] European Commission 'Better Regulation and enhanced Impact Assessment', Information note from the President to the Commission, Brussels, 19 June 2007

4 SUBSTANTIVE REVIEW

4.1 Assessing policy impacts

Recognition of the linkages between outcomes/decisions and processes/procedures is a major part of the rationale for requirements that Impact Assessments should accompany policy initiatives which have been introduced by the UK and EU governments in recent decades.

As already noted, there are some differences among countries and jurisdictions concerning guidance on good-practice for the conduct of the assessment of policy impacts. Nevertheless, a number of core exercises and questions can be identified, all of which are explicitly incorporated into current EU and UK guidance on Impact Assessments:[11]

- Identification of the problem.
- Identification of the relevant public policy objectives.
- Specification of alternative options potentially available: it is usually indicated that 'do nothing' should be explicitly considered as one of these policy options.
- General evaluation of impacts; which involves identification of who is likely to be affected, and by how much, leading to a wider consideration of the costs and benefits of alternative options.
- Risk assessment; including for example assessment of the potential for unintended consequences and of the various things that might go wrong with any particular policy initiative.
- Assessment of future enforcement and monitoring arrangements.

Our discussion of the substantive issues is set out in a manner that seeks broadly to follow this structure. Thus, we have sought to determine whether or not it is possible to identify, in relevant materials produced by the Department of Health:

- the nature of the problem that the policy measures are designed to address;
- the underlying policy objectives;
- the development and assessment of alternative options;

[11] Other factors which should also feature in any impact assessment include: equity and fairness; small firms' impact test; competition assessment; enforcement and sanctions; consultation; monitoring and review.

- the assessment of impacts on different sectors and groups; and finally
- the extent to which possible risks or unintended consequences of the policy have been factored into the analysis.

We are unable to comment on other aspects of the policy development process – such as how the costs and benefits were balanced, or what the future enforcement and monitoring arrangements are likely to be – since the information available to us regarding these aspects of the new arrangements is insufficient to undertake such a task.

4.2 Identifying the Problem

Our review of the relevant materials indicates that no one specific 'problem' has been identified which the proposed new supply arrangements for generic medicines are intended to address. Rather, the new arrangements are considered to be part of a package of measures that seem to be rather loosely aimed at a set of general concerns regarding the prescribing and dispensing of medicines in Northern Ireland in both the primary care and secondary care sectors. Among the general concerns that appear to have motived the suite of measures proposed are:

- A perceived need to 'standardise' generic product use between the primary and secondary sectors. This follows from claims that the current medicines management system has resulted in, among other things: different choice of agents in therapeutic class; different generics and parallel imports being used in primary care; and confusion for patients.[12] The alleged lack of 'concordance' is perceived to lead to patient confusion about which medicines they should be taking and to result in patients not using the required products or potentially duplication of product use.[13] On this basis, it has been suggested that the elimination or reduction of product switching at each dispensing event can lead to enhanced patient safety.

- An overarching concern – first identified in the Appleby report – relating to the lower levels of use of generic medicines in Northern Ireland as compared to the rest of the UK.[14] Appleby noted, for example, that in 2003 41% of prescriptions dispensed in Northern Ireland were for generic drugs compared to 55% in England.[15] As a consequence, the DoH has sought to promote the increased use of generic medicines in the quest for significant reductions in NHS costs. And in this context it

[12] Presentation of Mike Scott and Jill Mairs 'Pharmaceutical Procurement in N.I' All Island Public Procurement Conference, 1st May 2007.
[13] See, for example, M Scott, M Timoney, J Mairs and others 'Safe Therapeutic Economic Pharmaceutical Selection (STEPS): development, introduction and use in Northern Ireland' Pharmacother 8 (2007), Supp.1 ,Page 318.
[14] J Appleby 'Independent Review of Health and Social Care Services in Northern Ireland' August 2005, page 82.
[15] ibid, page 81.

is notable that recent estimates suggest that generic prescriptions dispensed in Northern Ireland has now reached a figure of a little over 50% of all items dispensed.

- A related concern regarding the higher spend on prescription drugs per capita in Northern Ireland than elsewhere in the UK. This point was also identified in the Appleby report where it was recommended that new mechanisms should be introduced which involve the greater use of sanctions to tackle high prescribing costs.

- Concerns about the lack of an 'integrated' approach to generic pharmaceutical procurement in the primary sector. This includes a perceived case for a central procurement strategy that takes advantage of 'improved commercial leverage' to 'secure the best value for money' through the negotiation of 'NI prices' for generics.[16] In discussing this issue, reference is frequently made by public officials to the 'success' of new contract processes in the secondary sector, where it is estimated that savings of over £2 million per annum were achieved between 2004-2007.[17]

In addition to these general concerns, it appears to us that there is some anecdotal evidence to suggest that the new arrangements are intended to address a more specific concern; that community pharmacies in Northern Ireland are 'profiting' through the current generics procurement/dispensing arrangements. This suggestion has been made by the Chief Pharmaceutical Officer for Northern Ireland in discussing the proposed changes. He noted that

> *The community pharmacy contract was not designed for pharmacists to make profits through medicines procurement.*[18]

We will return to this important point below, but note immediately that it raises very different issues to those surrounding the levels of prescribing and dispensing of generic medicines.

The current level of service provided by pharmacies in Northern Ireland

Before considering the relationships between the 'concerns' identified above and the specific proposals for new tendering arrangements for generic medicines in the primary sector, it is useful briefly to consider these concerns in the wider context of pharmaceutical supply in Northern Ireland.

Studies commissioned to examine the level of service provided by pharmacies in Northern Ireland have concluded almost unanimously that the service provided is of a very high standard. For example, the Department of

[16] Presentation of Dr Mark Timoney 'Generic Medicines'.
[17] Presentation of Mike Scott and Jill Mairs 'Pharmaceutical Procurement in N.I' All Island Public Procurement Conference, 1st May 2007. As will be discussed later, not all of those we talked to shared this optimistic view of performance in the secondary sector.
[18] Dr Norman Morrow, quoted in "NI's generics deal – will it work?', June 2008.

Health commissioned a study of community pharmacies in 2000, which concluded that:

> *This is a very encouraging picture of community pharmacy services in Northern Ireland....There is a very high level of satisfaction with the current service.....The results clearly illustrate that the community pharmacy is exceptional in terms of accessibility, standards of service and dedicated customer patronage and is a sustainable resource that provides a unique foundation for further development.*[19]

The Minister for Health at the time endorsed the findings of the study noting that 'pharmacies are very much the 'open door' of our Health Services' and that:

> *Pharmacists' knowledge and skills across the broad scope of medicines management, makes them unique among health professionals. I want to better utilise these skills to help patients get the best out of their prescribed medicines. This is why we are currently funding an important medicines management initiative through community pharmacies. I am also impressed by the extent of information that patients receive when purchasing over-the-counter medicines. That is a crucial aspect of responsible self-care and evidence of the value-added services of pharmacists.*[20]

More recently, the *Public Attitudes to Health and Social Services in Northern Ireland* surveys in 2005 and 2006 concluded that almost 99% of respondents were satisfied with pharmacy services in Northern Ireland. This was the highest level of satisfaction recorded across all health and social service providers in Northern Ireland, and was significantly higher than the overall level of satisfaction with health and social services in Northern Ireland (which ranged from 78% to 82%), and higher than the other main elements of primary health services such as GP services or dental services.

One of the key messages of the Community Pharmacy survey and the Public Attitudes surveys was that accessibility/proximity of pharmacies and the pharmacy-client relationship were key factors in the very high level of satisfaction observed with current pharmacy arrangements in Northern Ireland.[21] Among the suggested areas for improvements to pharmacy services noted in the surveys were: better access, reduced waiting times, and more funding.

There seems to us to be something of a disjunction between this type of evidence and some of the concerns that were said by the DoH to have

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[19] Pricewaterhouse Coopers 'Community Pharmacy Activity Survey' June 2000, page 6.

[20] The Minister for Health, Social Services and Public Safety (Northern Ireland) 'Community Services Pharmacy Praised by Minister' News Release, 28 June 2000.

[21] Northern Ireland currently has the highest pharmacy coverage in the UK with one pharmacy serving an average of 3,362 persons, as compared to the UK average of one pharmacy per 4,835 per head of population.

motivated the proposals for central tendering. For example, we would have expected any significant problems arising from patient confusion resulting from different approaches in the primary and secondary sectors to have at least some negative impacts on satisfaction ratings for pharmacists. It is, after all, pharmacists who dispense the 'different' products to patients. Yet there is no sign in the survey evidence that this is the case. Thus, although 'patient confusion' is held by the DoH to be a material problem, we have not seen any convincing evidence that it is.

The need to identify a specific problem for which central tendering is an appropriate response

As indicated above, we have not found it possible, in our review of the documentary materials, to identify a clearly defined problem to which the proposed new central tendering system for the supply of generic medicines is an appropriate response. It is not sufficient simply to express general concerns about, say, the level of generic prescribing in NI and then simply *assume* that a new set of arrangements will improve matters in ways that can be expected to be better than alternative and unexplored policy options. For example, if central tendering is being introduced to address concerns about low levels of generic use in Northern Ireland, then the connection between central tendering and the achievement of higher levels of generic prescribing/dispensing needs to be more clearly developed and supported.

The Courts have become increasingly clear about the level of analysis that is required, as the following citation from a European Court of Justice judgment indicates:

> *Not only must the Community Courts, inter alia, establish whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it."* Tetra Laval v Commission[22]

- *Perceived problems relating to a lack of standardisation/concordance*

Whilst it is the case that, under certain implementations, central tendering for generics in the primary sector may address the DoH's concerns relating to a perceived lack of the standardisation of generic medicines use in Northern Ireland, it is unclear to us, on the basis of evidence we have seen, that such an approach is likely to be the most efficacious. There are likely to be a range of other measures that could be introduced to address concerns relating to standardisation/concordance.

[22] European Court Of Justice *Commission v Tetra Laval* C-12/03P, 15 February 2005.

In our view, as a preliminary step it is important to understand the nature of the sources of the patient confusion in order to consider what might be an appropriate and effective response: Is it insufficient information provided at the dispensing stage? Is it the presentation of the product? Is it the rate with which generic products are substituted for one another at the dispensing stage?

If, for example, concerns relate to the presentation of the product (which might be a particular issue for the elderly) then efforts directed toward the standardisation of the presentation of generic drugs – either through standardising the form or colour of the dispensing pack or the pills themselves – could arguably do much to reduce such patient confusion. Alternatively, if the sources of confusion relate to the extent to which patients are sufficiently informed about changes to the generic drugs being prescribed then efforts directed at improving the training and dispensing practices of pharmacists are likely to be an appropriate way forward. It is notable, for example, that a recent study of concordance in prescribing for patients with hypertension highlighted the important role of training of health professionals such as pharmacists to better understand and appreciate the views of different patients for whom the products are being prescribed.[23]

There is obviously a trade-off here between alternative policy options to address concerns about perceived patient confusion in relation to generic medicines. On the one hand, while central tendering offers one possible response insofar as it may, depending on how it is implemented, result in patients consistently being prescribed the same generic drug, this comes at a cost of a potential loss in diversity and efficiency resulting from the replacement of a competitive market process with a single buyer. Moreover, it seems to us that the notion that, because the availability of choice can lead to confusion (which it certainly can), choice should therefore be restricted, is markedly out of kilter with the central strands of current public policy, which place the emphasis on standardisation in the way relevant information is formatted and presented, *not on standardisation of the products on offer*.

More specifically, the introduction of central tendering for the primary care sector would replace a normal market process, characterised by significant numbers of incentivised buyers and sellers of generic medicines on each side of the market, with a market structure characterised by a single monopoly buyer (a monopsonist) with questionable incentives to get purchasing decisions right (e.g. the incomes and pensions of the relevant decision makers will be unlikely to suffer greatly if, in the event, they fail to secure value for money).

Standardisation is, of course, a familiar feature of more centralised, more bureaucratic arrangements, and it can have some potentially advantages in terms of lower costs. However, it is also the case that:

[23] C Bane, C Hughes, M Cupples and J McElnay 'The journey to concordance for patients with hypertension: a qualitative study in primary care' 29 Pharmacy World and Science (2007) page 534.

- Reduced product variety has economic costs of its own: consumers and buyers have preferences for products that may be thwarted by non availability.

- There is no guarantee that potential efficiencies will be realised, since standardisation can have the effect of damping price competition.

- In general, diversity in markets is a source of security of supply. Standardisation and monopolisation tend to mean that when mistakes are made they are more likely to have market-wide effects, whereas diversity tends to mean that individual mistakes matter much less.

In short, it is our view, that there are likely to be a number of different ways in which a problem such as lack of product standardisation/concordance could be addressed, which is one reason why the 'identification of the problem' stage of policy assessment is often one of the most important. Central tendering represents only one such possibility, and one which comes at a potentially large cost in terms of the loss in product variety and future risks to security of supply.

- *Perceived problems relating to a generic prescribing/dispensing*

From our review of the materials it is not immediately obvious to us – and it has certainly not been explored in relevant public documents – *precisely* how and why central tendering for generic medicines might be expected to lead to greater levels of generic prescribing/dispensing in Northern Ireland. In fact, at least on a *prima facie* reading, the available evidence might be interpreted as supporting the converse conclusion, that decentralised arrangements for the procurement of generic medicines are highly consistent with the promotion/facilitation of high levels of generic prescribing/dispensing in Northern Ireland. In the last three years alone the rates of generic dispensation have increased by over nine percentage points, to above 50% of all pharmacy dispensations in 2007/08.

In this context, it is notable that the observation in the Appleby report that there was, at the relevant time, a significant difference between the use of generics in Northern Ireland and England – which is one of the proffered reasons for the introduction of the proposed measures – assumes a benchmark target for high performance that is based on a system in which procurement of generic medicines occurs via decentralised market processes, in which pharmacists, with strong incentives to seek out best available prices, are responsible for procurement, rather than a centralised bureaucracy.

Indeed, when reforms to generic reimbursement arrangements were under consideration in England, the central tendering option was explicitly rejected.

At a minimum, these facts suggest that the procurement measures employed for generic medicines may not be strongly associated with the rates of prescribing/dispensing of generic medicines in the primary care sector; which in turn provides more than sufficient grounds for treating unsupported

contentions about positive effects from central tendering on generic prescribing with considerable scepticism.

Summary

It is not the purpose of the above comments to set out an assessment of the relative importance of different possible concerns regarding the current arrangements for the supply of generic medicines in Northern Ireland. Rather, if central tendering for the primary care sector is to be considered as a possible procurement method, our key point is the importance of the *prior* issue of *precisely* identifying the *specific* (not general) problem for which for which such an approach might potentially be considered to be a proportionate and effective response.

The importance of defining a specific problem is recognised by bodies such as the OECD, and it is notable that it is the first priority listed in the OECD Reference Checklist for Regulatory Decision-Making,[24] which states:

> *1. Is the problem correctly defined?*
>
> *The problem to be solved should be precisely stated, giving evidence of its nature and magnitude, and explaining why it has arisen (identifying the incentives of affected entities).*

Likewise, the proposed new EU Impact Assessment Guidelines state:

> *Policy options must be closely linked both to the causes of the problem and to the objectives. You should define the appropriate level of ambition for the options in the light of constraints such as compliance costs or considerations of proportionality.*[25]

More generally, the identification of a specific problem can itself be useful to those responsible for implementing a policy insofar as it provides a clear reference point, or anchor, against which the adequacy of the later analysis of proposed corrective measures, and possible impacts, can be assessed. By discussing possible weaknesses in the current procurement arrangements only in general terms, the DoH fails to provide this type of clear reference point, and in our view it is this lack of specificity that may have contributed to some of the serious misunderstandings that currently surround the proposed central tendering arrangements.

Bearing in mind that clear and precise 'identification of the problem' lies at the very start of policy evaluation processes, in other contexts where we have been asked to comment on impact assessments, we have found it useful to refer to an Irish proverb:

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[24] OECD 'The OECD Reference Checklist for Regulatory Decision-Making', page 1
[25] European Commission 'Impact Assessment Guidelines', 2008 page 32.

Tús maith, leath na hoibre.

(A good start is half the journey/work).

In this case, lack of clarity and precision in the identification of the relevant problems implies that, unfortunately, a good start was not made.

4.3 Identification of alternative policy options

It is now standard in OECD, EU and UK policy guidance on best practice in assessing new policy initiatives that the identification, and assessment, of a range of alternative options be made explicit in the policy development process. For example, the point is specifically noted in the proposed EU Impact Assessment Guidelines, as well as the OECD's Reference Checklist for Regulatory Decision-Making:

> *Considering a wide range of policy options will force you to think 'out of the box', and also provides greater transparency. It is a way to show policy-makers and stakeholders that alternative options that they may prefer have been analysed seriously, and to explain why they were not pursued. It becomes easier to explain the logic behind the proposed choices and to avoid unnecessary discussions of options that will not help to achieve the objectives.*[26]
>
> *Regulators should carry out, early in the regulatory process, an informed comparison of a variety of regulatory and non-regulatory policy instruments, considering relevant issues such as costs, benefits, distributional effects and administrative requirements.*[27]

To our knowledge, the identification and assessment of alternatives to the proposed central tendering arrangements has not occurred in this case, or at least has not been subject to any sort of public discourse. Rather, the proposed central tendering mechanism for the procurement of generic medicines for the primary sector appears to have been the only option presented by the DoH throughout the policy development process.

It is clearly the case that other options exist that might assist in the achievement of the general objectives being pursued by the Department of Health. The most obvious of these is to build on current procurement arrangements, since the high level of consumer satisfaction with pharmacies and the low level of generics prices in NI would appear, at first sight, to compare very well with many other jurisdictions in Europe, and we are not aware of any cases of adoption of central tendering where it is possible to point to significantly better outcomes.

The existence of other alternatives is highlighted by the range of options considered by the Department of Health in England when seeking reforms to

[26] ibid, page 83.
[27] OECD 'The OECD Reference Checklist for Regulatory Decision-Making', page 1.

arrangements for the reimbursement of generic medicines, starting in 2001. Throughout that process a number of alternatives were considered, and the Department of Health (England) commissioned work to explore the relative merits of a range of possible options. Following a critical assessment of the possibilities, the resulting study set out no less than six different alternatives for reform, of which central tendering for generics was only one possibility. These were:

- *'Do nothing', except perhaps attempt to recoup any returns in 1999 of those in the supply chain that are considered excessive.*

- *Reform the reimbursement system by:*
  - *expanding the Drug Tariff basket to include the other large manufacturer, the third national full-line wholesaler, as well as some larger short-liners;*
  - *removing Category D;*
  - *reforming the Discount Inquiry, in particular by designing different inquiries for independent and for integrated pharmacies.*

- *Improve transparency through various types of information requests:*
  - *requiring price and volume information from manufacturers and wholesalers;*
  - *making better use of endorsement information;*
  - *IT solutions.*

- *Reform the licensing regime for manufacturers, to facilitate entry.*

- *Enforce vertical separation between integrated wholesalers and pharmacies.*

- *Use centralised purchasing by the NHS, either for all drugs, or for those in shortage.*

It is not the purpose of this Review to consider in detail the substantive merits of alternative policies, and nor are we suggesting that these proposals might be suitable in the Northern Ireland context. The point here is simply that in considering substantial changes to how generic medicines are procured and distributed, the Department of Health in England engaged in a fairly extensive evaluation exercise.

Nothing similar appears to have occurred in Northern Ireland, and the policy process appears to have been at variance with impact assessment guidelines.

4.4 The assessment of impacts, including risks and uncertainties

The recognition that new policy measures or initiatives can directly, or indirectly, affect a range of sectors and groups in a community, has been a principal driver behind the push for the more widespread use of regulatory

impact assessments in the policy process in the in UK, EU and elsewhere in the OECD.

The critical importance of assessing the possible impacts of policy measures on different groups is widely acknowledged in published guidance. For example, EU guidelines on Impact Assessments say that:

> *In your analysis of impacts, you should address the likely economic, social and environmental impacts - both intended and unintended - for each option, as well as potential trade-offs and synergies. The ultimate aim of this analysis is to provide clear information on the impacts of the various policy options as a basis for comparing them both against one other and against the status quo, and possibly for ranking the options in relation to clearly identified evaluation criteria.*[28]

Our review of the relevant materials associated with the proposed introduction of central tendering for the procurement of generic medicines in Northern Ireland indicates very limited reference to the expected impacts and effects of such arrangements. The extent of reference to possible impacts appears to be limited to the possible economic benefits associated with the introduction of the more general Pharmaceutical Clinical Effectiveness programme. This is vague in the extreme. In particular, we were unable to identify any significant assessment of the possible impacts of the new generic procurement arrangements on:

- Pharmacy services.
- End consumers and communities, via impacts on pharmacy services.
- Wholesalers, of all types.
- Generics suppliers/manufacturers.
- Branded medicine suppliers/manufacturers.
- Competition in the relevant markets.

Given that the implementation of the new arrangements might reasonably be expected to have significant effects on most, if not all of the above, the failure to consider the possible consequences of the proposals seems to us to be a manifest oversight on the part of the Department of Health.

The extent, and robustness, of evidence on impacts

There is very little robust evidence in the relevant materials on the expected economic benefits and costs associated with the proposed central tendering arrangements. The claims of cost savings associated with the new arrangements are anecdotal in nature, and are not supported by detailed

[28] European Commission 'Impact Assessment Guidelines', 2008 page 35.

reasoning, calculations or citations of relevant experience in other jurisdictions.

We found one reference made to possible global (reimbursement) cost savings that might be associated with changes to new arrangements for the procurement of generic medicines, in a letter from the Generic Medicines Tender Oversight Group to companies invited to tender for the supply of generic medicines, where it is noted that:

> *Over the CSR 2008-11 period, it is planned that a programme of generic prescribing, generic substitution, central contracting and Tariff adjustment will be required to realise £6.8m/£7.3m/£7.8m efficiencies respectively, across the 3 years of the CSR programme.*
>
> *These savings will accrue across the combined spending of the primary and secondary care sectors on these products, and it is recognised that there is the potential for adjustment of spending between sectors to facilitate an overall savings benefit. This process will be enabled by the above referenced tender...*[29]

We have been unable to find any analysis or report in the public domain which supports the estimated efficiencies noted in this letter, and which allows for the underlying assumptions or reasoning employed to estimate these savings to be independently verified. We note that the stated numbers are linked back to the wider programme of reform, and it is therefore not possible to assess how big a contribution is expected from central tendering/contracting. Again, therefore, there is an almost complete lack of transparency.

Assessment of risks and possible unintended consequences

Since we can find no clear and precise statement concerning expectations of the intended effects of the proposed new arrangements (for example, on the various stakeholders identified), it is unsurprising to find a lack of any analysis of the risks and possible unintended consequences of the changes.

Once again, we find that, although the consideration of the risks and uncertainties associated with policy choices is regarded as a key element of the assessment of impacts of new policy under EU and UK guidance, the DoH appears to have gone down a different road.[30] One important consequence of this omission is that it serves to further increase the risks of something going wrong, since one of the purposes of the risk assessment exercise is, by identifying potential problems, to facilitate adjustments to policy options which might serve to mitigate the risks involved.

In our view, we believe that this may be the most fundamental of the deficiencies we have identified. There are very general reasons why

[29] Letter of 27th June 2008 from The Generics Medicines Tender Oversight Group to Companies who have been invited to tender by RSS for the Supply of Generic Medicines to NI Health and Social Care.
[30] European Commission 'Impact Assessment Guidelines', 2008 pages 21 and 35.

arrangements based upon monopolisation and centralisation might be expected to respond less well to uncertainties and shocks than more decentralised arrangements for allocating economic resources, and, in consequence, to be more vulnerable to shocks in the market. In their report for the DoH in connection with reform of generic reimbursement in England, *Oxera explicitly referenced security of supply problems as one of the potential pitfalls of central tendering/contracting*, and we agree with that assessment.

The DoH appears to have proceeded in a way that is oblivious to some widely recognised risks. We do not think that, in the light of the facts, it can be denied that the central tendering/contracting proposals create risks of harm to supply side incentives and of distortions of competition in generics markets. Effective competition in tendering relies on attracting suppliers into competitions, and it is manifestly damaged by measures which discourage participation, as the proposals appear to have done.

Reduction in supply side participation, leading to increased concentration on the supply side of generics markets, is only one of the potential risks that are involved in moving toward monopolisation of the demand side of NI generics markets. We set out below some of the questions that we believe should have been asked by the DoH, as part of the risk assessment of the proposals

- *Economic impacts*

  - What is the likelihood of wholesale generic prices rising following the introduction of procurement measures, for example as a result of a contraction in the number of suppliers?
  - What is the impact of distribution costs being incorporated into generic reimbursement prices? How does this impact the viability of businesses operating at different stages of the supply chain, such as pharmacists?
  - How will the new the arrangements impact on the costs of wholesalers, and will this alter the structure of competition in the market?
  - Will the arrangements impose additional transaction or compliance costs on suppliers, wholesalers and pharmacists?
  - Will the new arrangements likely result in the withdrawal of certain products or services from the market? If so, what is the risk of harm?
  - Are the new arrangements likely to impose additional administrative complexity on generic suppliers, wholesalers or pharmacists? If so, what is the expected magnitude of the additional requirements?
  - How might the new arrangements impact on innovation or research and development?
  - How might the new arrangements impact on the quality or availability of the services that consumers receive from pharmacists?

- *Impacts on competition*

  - What are the possible long-term impacts on the number of generic suppliers operating in Northern Ireland as a result of the restriction in the number of eligible suppliers in the tender process?

- What is the likelihood that the new arrangements, including changes to the way in which pharmacists are renumerated for generic supply, will result in a restriction in the size of the community pharmacy market?
- How will wholesalers procure generic medicines and is this likely to lead to a change in the market dynamics which will impact on competition?
- How might the new arrangements alter the incentives for entry into the generic supply market?
- How might the new arrangements affect the incentives for entry or expansion in the pharmacy market?

- *Social impacts*

- How the new arrangements might impact on the supply chain, and, in particular is it likely that some geographic areas or regions may be subject to greater incidences of shortages?
- Given the importance of accessibility and proximity to customers of community pharmacies, how might the proposed arrangements impact on the availability of pharmacy services?
- Will the proposed arrangements have any likely impact on the quality of service offered by community pharmacists? For example, will it impact on the level of training given to staff, or on the knowledge and quality of information that a community pharmacist has about specific products or services?

- *Distribution of impacts*

- Will the new arrangements have disproportionate impacts on generic suppliers of different size?
- Likewise, will the new arrangements have disproportionate impacts – in terms of access and incentives to invest – on smaller pharmacies relative to larger pharmacy chains?
- How will the administrative burdens associated with the proposed new arrangements impact on pharmacists of different size?
- How will the new reimbursement arrangements work? Will they have different impacts on pharmacists of different size?

The above list of issues is not intended to be exhaustive, and there may also be other significant questions/issues which should have properly been considered by Department of Health when introducing the new arrangements for the supply of generic medicines. Once again, the approach adopted in Northern Ireland can be directly compared with that of the Department of Health in England when considering the possibility of central tendering, among other options, for the supply of generic medicines. In the latter case, the possible changes were recognised as being 'fundamental' in nature and therefore the Department of Health's approach was to take into account the impacts on various stakeholders.[31]

[31] See partial RIA attached to July 2001 document Annex c page 44.

4.5 Immediate risks and uncertainties that should have been considered

Although it is not possible to undertake a full risk assessment on the basis of the limited information currently available to us, it is possible to consider those risks which, on the basis of experience elsewhere and in other sectors, we consider to be the most important to identify and assess in the context of a proposal to introduce central tendering for generics. We touch on four such risks briefly below.

Risks to community pharmacy and patient safety

It is recognised that the changes brought about by the introduction of central tendering are likely to have a profound impact on the current business operations of community pharmacists. Most particularly, it is likely to be the case as a result of the introduction of central tendering measures, community pharmacists would suffer a loss of revenue. This prospect of pharmacists not being able to derive financial benefit from medicines procurement has, as noted earlier, been welcomed by the DoH.

Nevertheless, in response to the potential reduction in revenue community pharmacists will likely have to re-focus their business activities. This is because, as is generally well understood, net revenue obtained from medicines procurement is used by community pharmacists to support a range of other activities. Should pharmacy arrangements established in the wake of the introduction of central tendering provide insufficient net revenue to cover the costs of these other activities, it is to be expected that there would be contraction in the community pharmacy segment. In some situations the retrenchment might reduce the quality of services that pharmacists can offer patients; in other situations it could potentially lead to adverse impacts on patient safety; and in yet others it might simply lead to pharmacy closures.

The risks here have been explicitly identified by Teva:

> *We believe that the proposals will not support a vibrant pharmacy industry in Northern Ireland and could ultimately damage their interests and hence those of patients.*[32]

Risks to security of supply

As discussed elsewhere in this review, the very real risk exists with central tendering processes that, should they not be designed and implemented in an appropriate fashion, there can be risks to the security of supply for generic medicines. This potential risk was identified by both the Welsh Auditor General and in the study undertaken by Oxera for the Department of Health in England. In addition, this risk was identified as a particular concern by stakeholders in the May and July Question and Answer sessions.

[32] Open letter from John Beighton, Managing Director of Teva UK Limited to the Minister for Health, Social Services and Public Safety 25 July 2008.

Risk of increased generic prices

A further risk which is addressed more fully in the following section is that the way in which the central tendering process is designed and implemented may lead to potential increases in generic drug prices over time. The reason for this is simple. In replacing a system in which many buyers and sellers interact frequently with a procurement process where sellers interact less frequently with a single buyer, the potential exists that, over time, the participation rates of sellers in the tendering process may be reduced; for example, because of the costs of tendering or because they perceive themselves to have only a limited chance of being successful (this issue is discussed further below). In a nutshell, should this occur the market for the supply of generic medicines will tend to become more concentrated, which in some contexts will give the suppliers the incentive and ability to exploit their market power by raising generic prices.

Risks associated with dynamic structural change to the sector

A final immediate risk that should have been considered prior to the introduction of the central tendering arrangements is the possible adverse impacts that the process might have on the interaction between the primary and secondary care sectors, which ultimately might impact on patient choice and safety. For example, there remains substantial uncertainty about whether tender awards will be made for the same product to suppliers who operate in both the primary and secondary care sectors (joint awards), or whether generic suppliers who do not participate in a secondary care tender will still be eligible to participate in a primary care sector for the same drug. Moreover, there are questions about how the pricing of awards will be made for the same drugs across the two sectors; for example, is it the expectation of the DoH that they would expect to see similar prices for generic drugs in both sectors? If not, how do they intend to structure the tender processes to allow for similar drugs to be priced at different prices?

There are a range of other issues relating to the likely structural change to the sector which have been identified by various stakeholders but which the DoH has not yet adequately addressed. For example, the issue of what role, if any, wholesalers are likely to play in new arrangements has hitherto been completely ignored. As such, no assessment has been presented of what the potential impacts associated with the loss of the generic wholesaling sector in Northern Ireland might be.

Finally, there are a range of issues associated with how the DoH intends to prevent the trade of generic drugs from other jurisdictions, and, in particular, how it will seek to prevent some community pharmacists from procuring generic medicines from outside the central procurement system. To the extent that such practices become widespread this is likely to have substantial effects on the distribution of the impacts across community pharmacists operating in different areas, with resultant knock-on effects for patient service and safety.

5 THE USE OF CENTRAL TENDERING FOR GENERIC MEDICINES

The adoption of centralised tendering/contracting processes for the procurement of supplies by a public authority or a commercial organisation that is, in effect, the only or the major buyer of the products or services in a particular, relevant market is an issue that has been considered in a number of different economic contexts, and there is a wide range of analysis and experience to draw upon. So far as we can see, the DoH has not made significant use of any of the relevant material, but in this section we draw attention to some of the relevant points, focusing particularly on what have been identified as some of the major risk factors. As just explained, analysis of the potential risks is of critical importance because it can provide information that might be used to mitigate some of the risks; and avoidance of such analysis is likely to lead to the exposure of taxpayers and consumers/patients to otherwise avoidable risks.

Our discussion in this section is necessarily general in nature because of the limited information in the public domain about how the central tendering process has been developed or is expected to be implemented in practice. As indicated earlier, the DoH has taken an approach in which it has, in effect, left many implementation details, and a number of highly significant consequential changes to other aspect of policy (e.g. pharmacy dispensing fees), until a late stage in the process. As might reasonably have been predicted, the resulting policy uncertainty has made it extremely difficult for potential suppliers to form expectations on which they can sensibly bid (as has been explained to the DoH by several parties).

Given this situation, we begin with a general discussion of some of the conceptual issues associated with the use of tenders/auctions in procurement processes. This is followed by a consideration of some of the competition issues that can be associated with central tendering arrangements. Finally, we briefly consider some of the practical issues associated with the use of centralised tendering for the procurement of generic medicines, which might be expected to have impacts on its effectiveness, and on observed outcomes, in practice.

5.1 Thinking about tendering issues in a European context

In a European context, the introduction of tendering or contracting arrangements by a public authority has frequently been part of a liberalisation process of one sort or another, whereby 'markets' that were previously closed to most potential suppliers have been 'opened up' to competition. A familiar case is when a public body has previously 'self-supplied' a particular service (for example, refuse collection), but chooses instead to put the service out to competitive tender. In such cases a market that was previously monopolised on both sides (demand and supply), is converted into one in which, if

arrangements are implemented effectively (and see further below), there will at least be competition on the supply side.

We make these obvious remarks in order to make the equally obvious point that the NI generic market is not characterised by monopolistic arrangements. Generics prices are determined via a process of open competition in which many suppliers and potential suppliers compete for the business of many pharmacies. The introduction of central tendering in this context, therefore, implies taking a step backwards, from a more liberalised to a more monopolistic form of price determination.

Although manifestly obvious, we can see no indication in the relevant documentation that the authors of the proposed arrangements have taken these facts into account. We can see that the point has been made to the DoH, but can see no evidence that its significance has been recognised and understood.

5.2 General issues with the use of tenders in procurement processes

There is a large body of economics literature – both theoretical and empirical – which examines various aspects of tendering processes, and, in particular the circumstances and conditions under which the use of auction-like arrangements are likely to result in specific outcomes being observed in practice. This literature has been informed in recent years by the increasing use of these mechanisms in public policy and in public procurement.

In what follows we identify and briefly discuss some of the key 'headline' points that emerge from this literature, which we believe are most relevant to assessing the possible risks that might be expected to be associated with the introduction of central tendering for the procurement of generic medicines across the whole of the generics market, covering primary as well as secondary care, in Northern Ireland.

Recognising the different forms of potential arrangements and the risks of 'design failures'

It is important to recognise that there is not one form of 'tendering' arrangement and that the type and design of a specific bidding process can have significant impacts on the outcomes observed in practice. Tendering processes can take many forms and the ways in which they are structured can impact how effective they are as a procurement device. The specifications and rules regarding elements of the auction process raise issues such as: who may participate in such a bid (open or restricted), whether bids will be sequential or simultaneous, whether bids would be sealed or open, whether bidders may submit multiple bids, and whether there is a 'winner-takes-all outcome' or there can be several 'winners'.

To give a quick flavour of some of the design options, it can be noted that one common type of procurement process is the traditional sealed-bid tender, where would-be purchasers/suppliers are invited to submit bids for a specific

product, one of which will be declared the winner. In the simplest case, for example, sealed bids may be invited for a work of art, and the piece may be sold to the highest bidder.

Another common auction process employed in practice is the so-called Dutch auction, in which the price is gradually reduced – by the auctioneer, not by sequential bidding – and the first person to offer to buy at the last quoted price is the winner.

Further potential diversity is introduced when more than one thing is being sold or bought. Thus, the auction rules might specify that every successful bidder for one or more of a set of items must pay the amount that they have bid ("pay as bid") or that the amount to be paid by each and every winning bidder is the lowest winning price or, alternatively, the next-to-lowest winning price ("cleared price").

The complexity associated with tender design – and the strong linkages between the design and the observed outcomes – is not always recognised in discussions about the use of tenders in public procurement. Yet the empirical evidence is clear, as can be seen, for example, by looking at the outcomes of central tendering processes for, say, radio spectrum. Spectrum auctions across jurisdictions have opted for a range of different designs, and the differences in outcomes have been very wide indeed, varying from the high prices paid in contests such as that held in the UK to near zero prices, for very similar products, in other jurisdictions.

Given these points, we would have expected that, in exploring the option of introducing central tendering, the DoH would have devoted significant effort, including in particular via consultation, to exploring the alternative tender designs that were potentially available, their consequences, and their risks. That does not appear to have happened, yet the risks of 'design failures' are clearly very real.

Skill sets, resources and incentives

The extension of central tendering to the primary care sector could be expected to lead to a step jump in the complexity of procurement arrangements, and would inevitably pose much more difficult managerial challenges than hitherto.

Purchasing is a commercial function dependent upon particular skills. In competitive markets, the development and application of these skills is incentivised through the additional financial returns that are available from effective purchasing. These points apply whether purchasing is handled through a bargaining process or through a tendering process. In the latter case, for example, there are strong commercial incentives to get tender designs right.

Incentives become much more problematic when procurement is monopolised. For a commercial monopsony there will remain the carrot of

higher financial returns if costs are reduced, but what will be missing will be the pressure of competitors engaged in similar tasks. As Adam Smith put it:

> *Monopoly, besides, is a great enemy to good management, which can never be universally established but in consequence of that free and universal competition which forces every body to have recourse to it for the sake of self-defence.* (Wealth of Nations, 1776.)

Where the monopsony resides in a public authority, there will be an absence of external pressures from competitors *and* an absence of strong incentives for better cost performance. As John Stuart Mill famously expressed it in one of the classic works of economics:

> *All the facilities which a government enjoys of access to information; all the means which it possesses of remunerating, and therefore of commanding, the best available talent in the market—are not an equivalent for the one great disadvantage of an inferior interest in the result.* (Principles of Political Economy, 1848).

The problem with this old wisdom is that, whilst it is continually being revalidated by experience, it is also continually being forgotten by policy makers.

In NI, as in other parts of the UK, central tendering has been used in the secondary care sector, where the issues are much less complex than in primary care, but we have seen no substantive analysis of either its performance to date or of proposals to improve its performance in the future. Moreover, we have been told that contracts for supplies to the secondary care sector have not been re-negotiated as planned, for reasons that have not been publicly explained. Particularly given the tendency toward falling prices for established generics products, there seems to us to be at least a possibility that existing secondary care procurement processes are not being managed effectively and that the use of taxpayers resources is not being optimised. If that is the case, it would serve as a warning of possible, underlying problems in dealing with a much simpler set of problems than would be involved in tendering for primary care supplies. If it is not the case, it would seem to us advisable that the performance of secondary care tendering is fully analysed and publicly discussed, so as to build confidence in the process going forward. To proceed by simply ignoring the evidence of risk would, in our view, be reckless.

The implication of central tendering for prices

To summarise, the introduction of central tendering for generics across the whole of the NI market would represent a form of monopolisation, in which the existing, competitive price determination process would be replaced by a price determination process that would be heavily influenced by the discretionary choices of a small number of public officials.

Economics textbooks tend to suggest that monopolisation of the demand side of a market will lead to lower prices and to a corresponding restriction of supply. Whilst the former might be considered desirable from the perspective of a budget constrained procurement department or agency, the consequential restrictions of the supply side are necessarily harmful. In the specific context of pharmaceuticals, the immediate policy worries are likely to focus on continuity and reliability of supplies, which might be adversely effected by the monopolistic 'squeeze'.

However, prices and supplies can also be expected to be influenced, possibly quite substantially, by the design of the tender process. That is, discretionary choices over the detail of the arrangements can matter quite a lot, and once this factor is taken into account, it is quite possible that, notwithstanding the apparent buyer power associated with monopolisation of the demand side of the market, prices can be significantly higher than in a competitive market.

Radio spectrum auctions again show that this is a real and practical risk of poor tender design. In the spectrum case, the public authorities have been sellers, yet in some cases, notwithstanding the monopoly, outcome prices have been very low. The analogue of this effect in situations where the public authority is a buyer is an outcome in which bid prices turn out to be excessively high.

Given that the evidence is so clear, we do not think that there is any need to dwell on the theoretical reasoning that can explain the perverse outcome (increased buyer power leading to *higher* prices). However, the following summarise one or two of the principal mechanisms by which this can come about:

- Participation may be deterred by the costs of bidding, particularly for smaller suppliers, leading to a reduction in supply-side competition.

- Participation may be deterred by imprecision and uncertainty surrounding the 'rules of the game'. Administration of complex contracts is an activity that is very similar in nature to market regulation, and it is well known that regulatory uncertainty (uncertainty about the application of discretion) can have powerful, negative effects on supply.

- Participation may be deterred by tender rules that make it more difficult for higher cost suppliers to win. Whilst at first sight it may appear desirable that lower cost suppliers should always win, a moment's reflection will identify a problem: if higher cost suppliers don't compete, the outcome may be fine in terms of cost efficiency but very bad for the buyer in terms of prices (eg because the low cost suppliers win, but at high bid prices that would, if higher cost suppliers had participated, have been undercut).

- Precisely because central tendering involves the exercise of market power, and is therefore potentially open to the abuse of that market

power (including by public authorities), public sector tendering processes tend to be 'rule-bound', for example to meet EU legal requirements. Depending on the design of the arrangements, there is a corresponding risk that the rule-bound demand side of the market is easier to 'game' by suppliers.

These are intended to be illustrations only, but we believe that they should nevertheless be relevant considerations for the DoH, particularly given the history of some major failures in public procurement processes more generally (i.e. in other sectors and activities). To date, we do not believe that the prospect of the proposed arrangements being gamed has been a major risk, but that is largely because the 'rules of the game' going forward have been left unclear, undefined, imprecise and uncertain. For example, more than one stakeholder has pointed to the lack of any framework of thinking concerning the future of pharmacy reimbursement under the new arrangements, without which it must be impossible for generics suppliers to construct meaningful business plans.

The lack of clear rules, and the associated uncertainties, are themselves are a deterrent to suppliers. To address the adverse effects of uncertainty, clearer rules are required, but then care would need to be taken not to design a set of arrangements that are vulnerable to gaming. Our point here is simply that the trade offs need to be acknowledged and appropriate risk assessments made.

The promotion of supplier market power in the longer term

One issue that has been much studied in sequential auction/tender processes is that success by a supplier in one tender round can raise the chance of success in later tender rounds, whilst failure in one tender round can reduce the chance of success in later tender rounds. This occurs because of the existence of sunk costs, including information costs, which, even if relatively modest, can have large effects on outcomes. As a consequence, over time, the number of bidders may reduce.

The problem can be 'managed' to some extent, by sharing of contracts; but such a 'market sharing' approach itself tends to weaken initial price competition since, in effect, it makes purchasing outcomes less sensitive to bid prices (i.e. it creates market power in the short term to mitigate more extreme market power problems in the longer term). Again, given that the starting point in the supply of generics is one of competition, it can reasonably questioned whether there is any compensating benefit sufficient to counterbalance these risks.

We also note at this point one of the difficulties in assessing the early information available from the operation of tendering processes. Winning in the first of a series of contests for a contract can, for the reasons just given, have strategic value over and above any value intrinsic to the contract in the

first period. If this is recognised by bidders at the outset, competition in the first auction/tender will tend to be more intense because, in effect, competitors are seeking to acquire a prospect of market power or monopoly rents in later periods (there is “competition for monopoly”). On the other hand, competition in later periods will be muted.

Perhaps ironically, poorly designed auction arrangements that have the effect, over time, of reducing the attraction of participation to non-incumbents, can be expected to be associated with particularly keen bidding in the first round. In such circumstances, taxpayers and consumers may pay dearly later for what initially looks like a success. The point is, of course, that the impacts of alternative arrangements need to be evaluated on the basis of expected effects over a relatively extended time period, and not just the immediate impacts.

Tendering and the facilitation of supplier coordination

We have noted already that there is a difficult trade-off in public procurement exercises between, on the one hand, establishing the detailed and precise rules that can reduce uncertainty for potential bidders and can encourage participation, and, on the other hand, not creating a set of rules that are easily gamed by the bidding strategies of suppliers. This is part of a much wider issue to do with the effects of ‘repetition’ of similar contests on the evolution of competition.

A general result of the economics literature on tender/auction processes is that repetition of bidding contests in similar circumstances can lead to weaker price competition, via the development of patterns of co-ordination in bidding strategies. The most obvious example of this is the development of implicit 'buggins turn' arrangements, whereby there is some alternation in the aggressiveness with which different bidders strive to win contracts.

Bid rigging is, of course, illegal under the Competition Act, and it is to be expected that the OFT would be able to deal adequately with the more egregious attempts at coordination. Thus, the OFT is currently investigating a number of business practices in the building industry, a sector that is characterised by the widespread use of competitive tendering. Some of the effects of both tender design and of repeated tendering pricing conduct are, however, quite subtle, and it is not necessary for bidding strategies to fall foul of competition law for them to have upward effects on prices. Given this, it would seem sensible to us that public policy should seek to try and avoid situations in which problems are created which, although they may be addressable via general competition law, may require solutions that are partial and that can be expected to involve non-trivial implementation costs.

Long term supply awards and quality

In simple auctions/tenders in which commodities are bought and sold, there will be issues concerning the quality of the product which can give rise to uncertainties about its value (e.g. the authenticity of a painting, the condition

of a second-hand car). *Ex post*, there may be readjustments of prior assessments (e.g. the car is a lemon). In such cases, however, the quality of the commodity itself is given.

For contracts to supply over a period of time which involve a service element, the quality of supply/service will typically be determined *after* the price has been settled. In such cases, the effects of purchasing arrangements on quality incentives can become a serious issue. The supply of pharmaceuticals to the primary care sector is just such a case, since the service element is important: arrangements must be such as to lead to responsive, quick and reliable distribution of products to a relatively large number of locations, each accounting for a relatively small volume.

Potential risks to quality of service are particularly prone to arise when tender processes tend to give an undue weight to price when evaluating alternative bids. This can easily happen inadvertently, for example because a requirement on a public authority to 'objectively justify' its choices – a requirement that might exist because of concerns about misuse of power – could lead to an unnoticed bias toward price as a selection criteria because price appears to be more objective than more speculative assessments about likely future performance in regard to service quality.

From a bidder's perspective, a company that is contemplating the submission of a lower price offer might conclude that the offer would be profitable *if and only if* its planned quality of service was reduced a little. If the offer is posted, the implicit (planned) degradation in quality will likely be hidden from the buyer. Alternatively, the lower price offer might be posted in good faith, in the belief that performance standards could be met (and there are well documented biases towards optimism in these types of circumstances), but, *ex post*, the supplier may find it necessary to reduce quality in order to maintain financial viability.

In principle, quality and performance standards can be specified precisely *ex ante* and rigorously enforced *ex post*; and tender design can be changed so as to reflect quality differences when different suppliers, with slightly different products/standards, are competing for the same contracts. In practice, this is much more easily said than done, since precision in specification and ease of monitoring tend only to be economically sensible when dealing with very simple commodities or services.[33] One of the things that we believe is missing in the DoH materials that we have seen is a realistic assessment that of the extra complexity that will be involved in introducing central tendering for the primary care sectors, and we think that, if uncorrected, this will lead to risks to service quality.

5.3 Comparisons with other policy decisions

The points discussed above are not novel. Many of them were raised at the time that central tendering was one of the policy options under consideration

[33] The general problem is one of contractual incompleteness. For more complex goods and services, efficient contracts tend not to specify all obligations and responsibilities precisely in advance.

in the context of the reform of generics reimbursement in England. In the event, the central tendering option was rejected in favour of one that built upon the existing, competitive market structure.

Similarly, the Auditor General in Wales advised against the use of centralised procurement practices for generic medicines, and drew attention to a number of the risks that would be involved as follows:[34]

> *It would involve establishing centralised contracts and this in turn would bring risks and practical challenges for the Assembly's NHS Directorate:*
>
> - *centralisation could weaken the security of supply. It could remove some of the ability of the present system to deal with supply problems. Manufacturers and wholesalers may give priority to customers in other markets paying higher prices. Also, if changes to procurement arrangements lead to significant price differences, parallel trade between Wales and other countries could lead to shortages of medicines in Wales;*
>
> - *while centralised contracts for secondary care indicate that substantial savings are possible, as the lower prices are discretionary on the part of the pharmaceutical industry there is no guarantee that similarly low prices can be negotiated for primary care;*
>
> - *a reduction in primary care medicine prices may lead to a compensating rise in secondary care prices, so cancelling out some, if not all, savings overall*
>
> - *the achievement of lower primary care medicine prices will require significant effort and expertise on the part of NHS Wales in negotiations;*
>
> - *as centralisation would affect the roles and payment of pharmacists and other contractors, such changes would need to be reflected in their contracts with the NHS, and the Assembly will need to assess how the changes may affect wider pharmacy and medical services. The encouragement of the prescribing of medicines covered by centralised contracts also needs to be considered, and this may need to be backed by primary legislation;*
>
> - *changes to procurement arrangements that lead to lower prices may have implications for pharmaceutical industry investment in research and development for new treatments. It would therefore be appropriate for the Assembly's NHS Directorate to involve the industry's representatives in Wales in considering such changes.*

Whilst the Auditor General also drew attention to potential benefits, we note the overlaps between his concerns and a number of the risk factors that we

[34] Auditor General for Wales 'The Procurement of Primary Care Medicines' 20 March 2003, pages 1-2

have identified above. These serve to emphasise that the risks should not be taken lightly.

5.4 Summary

Running successful tenders is not a straightforward process. It requires a distinct skill set and, when the relevant contracts are complex in nature, as will likely be the case for contracts covering the primary care sector, administration of them is an activity that is not very much different from ongoing regulatory supervision of a market.

There is, therefore, plenty that can go wrong, ranging from the immediate problems that can arise from tender design failures (as in some spectrum auctions) to the chilling effects on market activity arising from uncertainty as to how future policy discretion will be utilised to possible security of supply and service quality failures (a risk associated with central tendering for generic medicines that has been identified in previous assessment exercises by Oxera and by the Auditor General in Wales).

The risks are greatly compounded by the fact that the introduction of central tendering would, in a very direct and obvious sense, amount to the monopolisation of the demand side of what is currently a vibrant market, and it would therefore be restrictive of competition. Further, there are a number of ways in which the monopolisation of the demand side of the market might feed through into secondary restrictions on the supply side, particularly by discouraging participation in the market by some suppliers and potential suppliers.

Given the importance afforded to competitive process in EU law, these are serious matters. Since we can see no clear policy objective for whose achievement the restrictions of competition would be indispensable, we are led to wonder whether the proposals are actually lawful. That is not a question for us to answer, but what we can say is that restrictions of competition that are not necessary for the attainment of relevant social objectives are an indication that there has been a failure of policy assessment.

6 CONCLUSIONS

Our main conclusions from the review are as follows:

a) We have substantial reservations regarding the process by which the new arrangements have been developed. Serious concerns about the scope and adequacy of the consultation process have been expressed by key stakeholders, and those concerns appear to be well justified on the evidence available.

b) Associated with lack of proper consultation processes has been the relatively poor quality of information and analysis provided to stakeholders regarding how any new arrangements might be expected to operate in practice. The brevity and opacity of responses to various detailed questions raised in stakeholder question and answer sessions illustrates the problems.

c) The approach taken by the DoH in leaving many, highly significant implementation issues to be resolved 'later' (which might be characterised as a 'leap before you look' approach) is at odds with best practice in policy development, which requires that the impacts of policy initiatives (which often depend heavily on implementation details), be fully thought through *before* those policies are adopted.

d) In our review of relevant documentary materials, we have been unable to identify any clearly defined 'problem' in the supply of generic medicines to which the proposed new central tendering system for generic medicines in the primary care sector might be considered a reasonable solution. Clear and precise identification of the perceived problem is recognised to be the starting point for effective impact assessments, and in this case the evaluation process appears to have got off to a bad start.

e) If it is the case that the proposed central tendering arrangements for primary care generics are being introduced to address a general concern about the relatively low level of generic use in Northern Ireland, we would have expected to see reasoning or evidence showing how the changes would affect that level, particularly given that England exhibits a combination of high generic usage and *decentralised* medicines procurement. No such reasoning or evidence appears to be available.

f) Irrespective of the problem to be addressed, we would have expected to see an evaluation of alternative options for addressing them. However, the proposed central tendering arrangements appear to have been the only serious option presented by the DoH. This is inconsistent with UK, EU and OECD policy guidance.

g) Whereas all stakeholders appear to agree that the DoH proposals could have far reaching consequences for community pharmacy, no assessment of these potential consequences has been undertaken and the relevant issues have been parked in a 'to be considered later' basket. Given the significance of community pharmacy for consumers in the primary care sector, and given the general public policy position on small and medium size business enterprises (of which there are many in pharmacy), the neglect of these potential impacts appears both unreasonable and irrational.

h) Similarly, potential effects on competition in the NI market for generic medicines have been ignored. Given that the status quo is characterised by a competitive generics market, with many buyers and sellers (or potential sellers), the introduction of central tendering is, as a simple matter of fact, a move toward a more monopolistic price determination process, in which prices can be expected to be much more influenced than now by DoH skills, DoH incentives, and DoH discretions. As such, it appears to run counter to the policies of liberalisation advocated and pursued by the UK, the RoI and most other EU Member States, and possibly also to European Competition Law.

i) We have not seen, in the documentary evidence, any substantive risk assessment of the proposals, notwithstanding that there are potential risks to, among other things: security and continuity of supply, prices, quality of service (at the pharmacy level) and competition. Given the importance of medicines to the community as whole, and to vulnerable groups such as the very elderly in particular, this seems to us to be a reckless way to proceed.

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George Yarrow is Chairman of the Regulatory Policy Institute, Oxford; Emeritus Fellow of Hertford College, Oxford University; Visiting Professor at the Newcastle Business School; a Board Member of the Gas and Electricity Markets Authority (GEMA, www.ofgem.gov.uk), the GB energy regulator; economic adviser to the Civil Aviation Authority; a member of the National Audit Office's academic panel on regulatory impact assessment; and a director of the companies DKY Ltd and Davison Yarrow Ltd. He also recently served on the Republic of Ireland's Aviation Appeals Panel, which handles appeals against regulatory determinations of airport charges.

After graduating from Cambridge University, he held appointments at the Universities of Warwick and Newcastle before moving to Oxford, where he spent most of his academic career. During sabbatical periods he was a visitor to Harvard University, the University of California at San Diego, and the University of Urbino. His principal work has been on the economics of privatization, regulation and competition, Among his books are: *Privatization: An Economic Analysis* (MIT Press) with Sir John Vickers, which has also been published in Spanish and Chinese translations, and *Privatization* (Routledge), a four volume anthology of papers with Piotr Jasinski. He has written numerous academic papers and policy studies on issues of competition and regulation.

Recent public lectures have included: The Enterprise Act (London), Electricity Market Reform (Paris), the Changing Dynamics of Europe's Liberalizing Energy Markets (Amsterdam), Modernization of EU Competition Law (London, to UK High Court and Appeal Court judges), Economic Assessment in Competition Law Cases (Berlin, to the Association of European Competition Law Judges), EU Energy Policy (for the annual ACCC conference, Australia), and Energy Policy: A Time to Stop Pretending? (in the Beesley Lecture series in London). In the second half of 2008 he will be speaking at the ACCC conference on general issues in regulation and on environmental aspects of energy regulation, and giving a Beesley Lecture on 'Discovering the value of water').

Recent policy studies have included work on: Regulatory reform and the promotion of competition in communications (DTI/DCMS, London), Economic regulation of air traffic management (DGTREN, Brussels), State aid and nuclear power (DTI, London), Assessing the burden of regulation on business (Cabinet Office, London), EU Member States Regulatory Impact Assessments (for EU Directors of Better Regulation), Regulatory instruments in farming and the agri-environment (Defra), Reverse eAuctions in NHS procurement (ABHI),

, and most recently The effects of maintaining price controls in liberalising markets (Australian Energy Market Commission), and The prospects for competition in the water services sector (Water UK).

Professor Yarrow has considerable experience of policy advisory work, both at international agency (OECD, World Bank, UNDP, etc.) and national government level. Areas of regulation covered by this work include: banking and financial services, communications, competition policy, energy, environment, health services and pharmaceuticals, and transport (air, rail and road).

In addition, he has a longstanding interest in competition law and policy, including having at various times acted as an advisor to enforcement authorities and to companies, at both national and at EU levels. He has given evidence in competition cases to the Competition Commission, the Office of Fair Trading, the High Court (e.g. in *Crehan* and *Arkin*) and the Competition Appeals Tribunal in the UK, and to the European Commission and the European Court of First Instance. His current cases include DRAM interface technology standard setting, the determination of mobile telephone call termination rates, and conditional discounting in the supply of microprocessors.

On the specifics of regulatory policy, Professor Yarrow has experience of virtually every major aspect of policy development over the past twenty years. He was economic adviser to the National Grid for the initial design of the transmission use-of system charges for the high voltage electricity grid, and later to British Gas for the development of similar entry/exit arrangements for gas pipeline capacity. Later, first as economic adviser to Ofgem and now as a board member of GEMA, and in addition to working on all aspects of price controls (gas transmission, gas distribution, electricity transmission, electricity distribution, system operator incentives, gas storage, meters) he has been involved in the full range of regulatory reforms introduced in the UK from the mid-1990s on, including: retail market opening, retail
market deregulation, gas storage deregulation, the new electricity trading arrangements, the new gas trading arrangements, the establishment of the first energy exchanges, the integration of the Scottish and England & Wales electric systems; and the enforcement of the Competition Act in the energy sector. In telecoms he has been a member of expert panels set up to assist UK ministers in the development of the new Communications Act and to assist EU Commissioners in the development of policy responses to technological convergence in communications. In air transport, he has been an advisor to the CAA for successive price reviews of Air Traffic Control Services and of London and Manchester airport charges.

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Chris Decker is Research Director at the Regulatory Policy Institute, Oxford and an Associate Research Fellow at the Centre for Socio-Legal Studies, Oxford University. Prior to returning the Institute in October 2007, Chris was a Principal Economic Advisor at the Australian Competition and Consumer Commission. Before that he was a research associate at the Regulatory Policy Institute, and also worked as an economic consultant. He currently acts an independent economic advisor to Ofgem and the Australian Competition and Consumer Commission and is a member of the panel of experts for the Commission for Energy Regulation (Ireland).

Chris's work is focused on economic regulation, competition economics and public policy. He has been involved in a range of research and consulting projects for both the public and private sectors, including for: the OECD; the European Commission (DG Transport & Energy); the Australian Competition and Consumer Commission; the Australian Energy Markets Commission; ENARGAS (Argentina); the South African Competition Tribunal; and in the UK, the Competition Commission, Department of Trade and Industry, Cabinet Office and Office of Gas and Electricity Markets. In addition, he has worked on projects for private organisations such as: British Telecom, British Gas, J-Power (Japan), and EPDC (Japan).

Recent research projects he has been involved with include: an impact assessment of the European Executive Agency for Competitiveness and Innovation for the European Commission; a study examining the prospects for competition in the UK water industry; a review of International approaches to transmission access for renewable energy; an assessment of the competitive and economic impacts of the introduction of the Single European Payments Area; a study for the European Commission on the development of implementation rules of economic regulation within the Single European Sky initiative; and two studies examining the impact of regulation on investment and innovation for the Department of Business, Enterprise and Regulatory Reform.

The major focus of his academic work has been on the issues relating to the application of economic techniques in regulatory processes and in competition law enforcement. Chris has a first class honours degree in economics from the University of Melbourne (Australia) and a PhD from the University of Oxford.