

REGULATORY POLICY INSTITUTE

The provision of nutrition supply services: an assessment of current NHS procurement arrangements in England

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1. Introduction

- 1.1. This Report evaluates current National Health Service procurement arrangements for nutritional supply services in England. The principal focus is on contractual procurement of these services in the secondary care sector, but, since the economic effects of the secondary sector arrangements and their implications for the NHS depend crucially on how they function alongside primary care arrangements, it is necessary also to take account of the latter. Specifically, the assessment takes particular account of the economic linkages between procurement decisions in the two sectors, which give rise to a number of important issues and questions.
- 1.2. Section 2 of the Report first sets out the most salient characteristics of the relevant products and services, of the market for such products and services, and of the current purchasing arrangements. It then identifies a number of issues to which current practices give rise. The material is mostly factual, although it becomes increasingly evaluative (in sub-section 2.4) as issues are identified and as linkages between different features of the economic context are identified and noted.
- 1.3. Section 3 contains more formal assessment of the procurement arrangements based on general economic reasoning and on comparisons with outcomes and approaches in other types of market where similar issues have arisen, including, but not restricted to, the health sector. The aim is to identify aspects of the procurement arrangements that, looking forward, offer scope for improved performance in meeting the objectives of the NHS as a whole.
- 1.4. A final section summarises some of the most important findings of the assessment and makes a number of suggestions as to how progress toward achieving potential improvements in performance might be made.

2. General background and context

2.1. The products

2.1.1. The products and services with which this report is concerned are those that form the subject matter of contracts between suppliers and the NHS, and are broadly termed “nutritional supply services”. The relevant products and services are more precisely delineated in the Procurement Guide (“the Guidance”) published by the Commercial Medicines Unit (“the CMU”), which is designed to support procurement groups and clinicians through the process of procuring enteral feeds and related goods and services, such as pumps, consumables, home delivery and associated support services¹.

2.1.2. For current purposes it is useful to distinguish three major elements of these suppliers:

- i. The medical nutritional products themselves, the “feeds”;
- ii. Complementary products such as pumps, giving sets and ancillary plastics;
- iii. A service element which includes home deliver, homecare and other associated services such as nurse training in the use of the products and the feeding system.

The feeds

2.1.3. The medical food products are principally divided into two distinct categories:

- i. Enteral tube feeds, which are fed directly into the patient’s stomach or intestine through a feeding tube.
- ii. Oral Nutritional Supplements (“ONS”), or ‘sip feeds’, which are for the patient to drink in the style of a juice or milk-shake, either as the sole source of nutrition or as a supplement to enteral tube feeding or normal eating.

2.1.4. The various feeds are differentiated by their nutrient content, energy density and targeted age group. This differentiation is necessitated by the differing demands and categories of patients. Some patients, for example, might require a feed containing fibre; some patients might be unable to digest whole proteins and require a peptide based feed; some patients might have an intolerance to a certain nutrient, such as lactose or gluten. Similarly, patients may be able to tolerate only short feeding times and therefore require a higher energy density feed, allowing the delivery of more calories per millilitre; and children or infants will need nutrient balances which differ from those of adults. Since they interact with the taste-buds, ONS are also differentiated by flavour, e.g. strawberry or vanilla.

¹ The Guidance, dated July 2014, is available from the British Specialist Nutrition Association website - <http://www.bsna.co.uk/documents/Procurement%20Guide%20for%20the%20Provision%20of%20Supply%20Services.pdf>

Complementary products

- 2.1.5. Complementary items, which include pumps, giving sets and ancillary plastics, are necessary for tube feeding, but not for sip feeding. This is a factor that gives rise to a degree of economic differentiation between the two categories of feed. There may also be further, technically induced differentiation, which also has economic consequences, if particular feed containers are compatible only with particular types of pumps, giving sets and ancillary plastics which need to be connected with the container and with each other. This is typically the case in practice.
- 2.1.6. Pumps are ‘CE’ marked medical equipment which electronically deliver feeds to patients. Distinguishing characteristics of pumps include their battery power; ability to control the flow-rate of the feed; ability to record volumes accurately; integrated alarm systems (audio, visual and vibratory) for e.g. indicating low battery, air in the line or an occluded line; readable display with access to data such as volumes to be delivered, volumes delivered and pump history. Pumps are re-useable for multiple feeding sessions.
- 2.1.7. ‘Giving sets’ describe the plastics and tubing that connect the feed bottle to the pump and the patient’s feeding tube. A typical giving set is only used for feeding sessions over a twenty four hour period, after which it is disposed of and replaced. Giving sets are precision manufactured to operate with the pump to minimise any errors in flow monitoring and volume delivery. Giving sets will therefore only be compatible with the pumps which they complement, in practice provided by the same supplier. Distinguishing characteristics/qualities include the degree of precision with which they can control rates and delivery, and (owing to constant replacement need) ease of opening connection and priming.
- 2.1.8. ‘Ancillary equipment’ describes the remaining apparatus and plastics associated with enteral feeding, the demand for which will vary from patient to patient. Such equipment may include stands and clamps for supporting feed bottles and pumps, adaptor plastics for using feeds provided by different suppliers, syringes for delivering feeds or flushing out tubing, backpacks which enable feeding away from home, and many other parts and pieces.

Associated Services

- 2.1.9. The service element to the supply varies depending on the particular requirements of different purchasers and the capacities of suppliers to meet all or part of the full range of requirements. Associated services might include: a pharmacy dispensing service for tube feeds and ONS; and ongoing periodic delivery service for giving sets and ancillary plastics either with or without the associated feeds; a homecare and nursing service, with face-to-face visits for patient training and review, tube intervention, routine device changing, and trouble-shooting; access to an IT support system and database for patient information and registration;

training of hospital and community dietitians and nurses on nutritional products, pumps and giving sets; and in some cases funding for NHS staff posts.

2.2. The market

2.2.1. The CMU, in its Guidance, characterises the market for nutritional supply services as “discrete” and “specialist” with only a limited number of suppliers. It estimates the current size of the market, in value terms, to be approximately £240 million per annum (£89m on tube feeds, £151m on ONS). As will become clear in the discussion below however, this split of the aggregate value between tube feeds and ONS, based on expenditures, is a misleading indicator of the relative contributions of the two market segments to the economic value of the relevant goods and services to the National Health Service.

Supply

2.2.2. According to the CMU, there are three suppliers in the market who provide all three elements of standard supply contracts (feeds, complementary items, associated services). They are Abbott Laboratories Ltd., Fresenius Kabi Ltd. and Nutricia Advanced Medical Nutrition.

2.2.3. There are also several additional suppliers of feeds alone, in distinct sectors such as infant formulas (SMA Nutrition (owned by Nestlé), Mead Johnson), or specialised ONS (VitaFlo (owned by Nestlé and also a supplier of metabolic feeds), AYMES International, Nualtra).

2.2.4. Until 2014 there was one supplier providing a combination of feeding pumps, ancillaries and a home delivery service (Covidien), but it has recently withdrawn this combined offering citing increased economic pressures and a diminished need for a stand-alone service provider in the community.

2.2.5. Estimates of current shares of Home Enterally Fed (“HEF”) patients suggest Nutricia has 53%, Abbott has 32% and Fresenius has 15%². Estimates of current shares of ONS patients suggest that Nutricia has 52%, Abbott has 23%, Fresenius has 9%, Mead Johnson has 8%, Nestle Nutrition has 4%, VitaFlo has 3% and AYMES International has 1% in this segment of the market³.

Demand

2.2.6. The Guidance indicates that there are approximately 38,000 patients in England currently requiring enteral feeding and associated services. Such patients are clinically diagnosed with, or at risk of, malnutrition, or are for any reason unable

² These estimates are derived by aggregating numbers of patients declared in contract documents for HEF supply services in England, along with the contract awards. Inferences/ assumptions are made where specific patient numbers are not available, such as assuming an average prevalence of 0.0004% in these cases. The estimates should properly be treated as rough approximations only.

³ Data from IMS, using sales to the community through pharmacy wholesalers. The data includes sales of specialised modular and metabolic feeds.

to eat food normally. Common reasons include difficulty swallowing, inability to digest proteins and fats (as can be the case with patients suffering from Cystic Fibrosis), or post-surgery difficulties with eating and digestion. Requirements for medical nutrition products may be of a short-term nature (e.g. where a patient is recovering from an illness or surgery), or may persist for a longer period of time (e.g. where the patient's condition is chronic).

2.2.7. Purchase of medical nutritional products and services on behalf of patients is performed by the National Health Service ("NHS"). Though different elements of the supply are functionally purchased from distinct budgets within the NHS (see more below), the ultimate principal on the demand side is NHS England, which has the characteristics of a dominant buyer. We understand that private medical companies are currently not major purchasers of nutritional supply services and that the overall demand for such services is therefore largely accounted for by NHS procurement.

2.3. Current purchasing practices

2.3.1. The principal mechanisms by which nutritional products and services are acquired by the NHS are:

- i. An NHS body undertakes a public procurement exercise and awards a contract for the supply of nutritional products and services required by that body to serve its patients.
- ii. A pharmacy dispenses feeds against FP10 prescriptions and is reimbursed by the NHS Business Services Authority.

2.3.2. The manner in which these two mechanisms complement each other and overlap is explored below. The current process has evolved in the last two decades from a situation in which all elements of the supply (products, equipment, associated services) were included in a single NHS list price, dispensed by pharmacies, and reimbursed by the central Prescription Pricing Authority (now the Prescription Services part of the NHS Business Services Authority). In 1995, however, the Department of Health issued executive letter EL(95)5⁴, which reformed the processes in related fields such as parenteral nutrition and which provided for certain specialised health services to be purchased contractually by Health Authorities. A later clarificatory letter⁵ explained that this policy was not intended to apply to the enteral feeding sector. Notwithstanding this clarification, in 1997 an invitation to tender was issued for the supply of enteral feeds and services via a contract with Avon Health Authority and this particular exercise in effect

⁴ A full text of NHS Executive Letter EL(95)5 is included in Appendix 4.2 of the MMC's report on a proposed merger between Fresenius and Caremark in 1998, available from the National Archives - http://webarchive.nationalarchives.gov.uk/20111202195250/http://competition-commission.org.uk/rep_pub/reports/1998/415fresenius.htm#full

⁵ Also reproduced in Appendix 4.2 of the above report.

became a pilot for the above, twin-track (via contracts, via FP10 prescriptions) approach to NHS procurement of enteral feeds.

- 2.3.3. Under the current structure of the health service, the contractual procurement process is undertaken by a number of NHS bodies: Hospital Trusts, Foundation Trusts or Clinical Commissioning Groups (“CCGs”) though a public procurement exercise. Very often the invitation to tender will be issued on behalf of a consortium of such bodies, or by one body contracting on behalf of a group comprising itself and others. In recent times, a number of private companies have been established in the form of procurement hubs that operate public procurement exercises on behalf of a group of NHS organisations comprised of Hospital Trusts, Foundation Trusts or Clinical Commissioning Groups. Such procurement hubs are normally not party to the resulting contract but provide administrative services to NHS organisations in relation to the tender process. In these latter cases, the demands/requirements for medical nutrition products and services are, in effect, aggregated and tendered and form the basis for a single tender. This is a form of what is known more generally as collective buying and the resulting aggregations of demand can cover a reasonably extensive geographic area, typically equivalent to an English county.
- 2.3.4. Methodologies governing precisely which products and/or services relating to medical nutrition are acquired by this public tendering process vary widely across England, as each NHS body/consortium tends to have its own idiosyncratic needs and processes; but, to the extent that there is a ‘typical’ contract, this will cover not only the supply of feeds, equipment and services to the secondary (hospital) care setting, but also the supply of any equipment and services that may be needed for patients in the primary (community) care setting. The specified equipment will broadly be the same across sectors, the service element of the supply to the hospital will primarily be training sessions on equipment and feeds for hospital based healthcare professionals and patients and on IT systems to manage patient data, while the service to the community will primarily be a home delivery service and a nursing/homecare service for patients on enteral feeds at home.
- 2.3.5. The contractual procurement of equipment and services in the primary sector in part derives from cost-saving initiatives in connection with EL(95)5, and reflects the overlap of primary and secondary care which is a characteristic of certain medical treatments, including enteral feeding. Thus, patients initiated on tube feeds in the secondary sector will frequently need to continue to require such feeds, and hence equipment and services, after discharge from hospital. The ‘typical’ contract does not cover the supply of the feeds themselves for patients in a primary (community) setting, although patients are typically discharged with sufficient supplies to cover a short post-discharge period. Rather, the supply of feeds in the community setting is governed chiefly by the FP10 prescription approach, further explained below.

- 2.3.6. On the supplier side, once the NHS body/consortium, the ‘procurement authority’, has issued its invitation to tender in accordance with public procurement procedures, the suppliers of products and services submit competing bids for the contract award. The award may be separated into lots, and suppliers may bid for any or all of such lots. The bids are evaluated according to predetermined criteria that, in accordance with public procurement law, are required to be transparent and contract(s) are awarded to the bid(s) which have been found ‘most economically advantageous’. This criterion is given operational meaning by means of aspecified weighted-scoring methodology that covers all aspects of the requirements. Specifically, scores are awarded for all components of the tendered requirements – feeds, equipment and associated services – and encompass both price and service quality.

Prescriptions

- 2.3.7. As noted above, the alternative mechanism by which medical nutrition products (and, historically, equipment and services too) are acquired by the NHS is via the prescription route. According to the NHS Drug Tariff, “in certain conditions some foods (and toilet preparations) have characteristics of drugs”. As a consequence, some ‘borderline’ products, which include as a category medical nutrition products, are included under Part XV of the Drug Tariff, following a recommendation procedure that will be discussed below. This allows nutritional products included in Part XV of the Drug Tariff to be prescribed by GPs via an FP10 form for patients in a community setting, in the same manner as if they were prescribing a pharmaceutical product.
- 2.3.8. In these cases, patients will be supplied with products by pharmacies. These may be community pharmacies which have acquired the products by way of a wholesaler, or may be specialist pharmacies, integrated within the manufacturer’s operations or providing ‘outsourced’ pharmacy services to the manufacturer. The pharmacy, as is the case for pharmaceutical medicines, dispenses the medical nutrition product against an FP10 form and is then reimbursed by NHS Business Services according to the Drug Tariff price of the product plus any dispensing and professional fees.
- 2.3.9. This prescription route for purchasing feeds therefore complements the secondary care contractual procurement arrangements in that it provides for the supply of feeds to patients within the community setting. The division between purchasing feeds by procurement and purchasing them via prescription and reimbursement is widely viewed as important for sustaining the role of GPs in community healthcare, in particular by supporting the principle of GP freedom of prescription, an important principle of wider NHS policy.

The 'typical' contract in practice

- 2.3.10. For tube fed patients, the normal practice is for patients to be initiated on feeds in the hospital setting, making use of supplies acquired via the contractual procurement process. The patient may then be later discharged from hospital into the community, either taking with them ancillary equipment such as their pump or having this pump sent directly to their place of residence in the community and enough supply of feeds and disposable plastics as they will require for the next 7-14 days. This equipment and product is part of the supply acquired by the hospital under the relevant contract.
- 2.3.11. If requiring tube feeding at home, the patient will then be enrolled by the hospital on the homecare service which forms part of the contract.
- 2.3.12. The patient on the homecare scheme within the community will acquire all further feeds needed beyond this two week period from their GP. The GP will prescribe a feed via the FP10 form, which in most cases⁶ will be sent to the specialist pharmacy of the supplier that has been awarded the contract pursuant to the public procurement exercised carried out for secondary care and dispensed against the form. The pharmacy will provide the dispensed product to the home delivery service provider. The service provider will deliver the feed and any associated disposables to the designated delivery location and will also then provide homecare and nursing services related to enteral feeding at that location. The service element is funded under the supply contract secured by public procurement, while the product is purchased according to the pharmacy reimbursement scheme and corresponding with the NHS list price of the product by the NHS Business Services Authority.
- 2.3.13. As above, under GP freedom of prescription, the feed prescribed in the community may be any supplier's feed. In practice, however, it is extremely common for the GP to prescribe the feed that has been recommended to them by the hospital dietitian, which will normally be the same product as used in the hospital. This may be considered important for continuity in the care that the patient receives after having been discharged into the community, and it has practical advantages deriving from the fact that suppliers' feeds tend to be fully compatible only with the giving sets and pumps that they also supply under the relevant hospital contract⁷.
- 2.3.14. ONS patients on the other hand are often initiated on feeds in the community, without ever having been a secondary care patient. Their circumstances might be rather different from patients needing tube feeding, for instance in the case of geriatric patients struggling to meet their daily calorie requirements; or they may

⁶ Although patients are entitled to take the prescription to a local pharmacy of their choice, if they so wish.

⁷ The pumps and giving sets associated with one supplier's feeds can potentially be used in conjunction with another supplier's feeds, but this will require that extra steps be taken, such as decanting the feed from one type of container to another or use of additional 'connecting' equipment.

be closely related, such as patients transitioning from tube feeding towards regular eating by way of sip feed supplements.

- 2.3.15. If a patient is initiated on ONS within the hospital setting or is transitioning from tube feeds to oral supplements within the community, then as above they may be included in the home delivery and homecare service provided for by the procured contract. In the same way as for tube feeds, patients will be prescribed products by their GP (who will usually liaise with the hospital dietitian) using the FP10 form. The form will be sent directly to the contractor's specialist pharmacy, where the products are dispensed for delivery to the patient's home by the contract service supplier. The supplier is also responsible for any necessary nursing services related to patients' enteral feeding.
- 2.3.16. Patients initiated on ONS within the community setting together with some patients discharged from hospital will not necessarily be enrolled on the homecare/home delivery service of secondary sector contract. Rather, some patients will obtain the products directly from a community pharmacy, and the GP's freedom to prescribe the products of different suppliers will typically be less constrained by factors such as the compatibility of equipment and feed containers and requirements for nursing services to support the patient in the use of feeds. Put another way, the GP's prescription decision can be expected to be less influenced by any local, secondary-sector contractual decisions taken in regard to ONS supplies, which is not to say that such influence can be expected to be entirely absent: what is to be expected is simply that, compared with the position for tube feeds, there will tend to be a higher proportion of patients obtaining ONS feeds from suppliers other than the supplier providing feeds to the local hospital(s) under the public contract.

The "off FP10" model

- 2.3.17. Beyond the 'typical' mechanisms outlined above, in practice some contracts may include the price of the feed to the community within the specific subject matter of the contract, and hence remove the requirement for the feed to be prescribed via the FP10 route. This is referred to as the "off FP10" or "off script" model of supply.
- 2.3.18. In these circumstances the supply of feeds, plastics and pumps to the secondary sector is contracted in the ways described above, with supply of feeds to the community secured at the same point. Off-script models vary from contract to contract, but in essence, communities are supplied with products and services by the contracted company without the involvement of a GP or pharmacist. The publicly procured contract will therefore include and evaluate a price at which the relevant NHS body will purchase products for use in the primary sector. This price may be the same as the FP10 price of the product as listed in the Drug

Tariff, but since there is no involvement of NHS Business Services, the contracting parties have freedom to negotiate a different figure.

- 2.3.19. The CMU notes in its Guidance that the legality of such contracting arrangements may be called into question as the removal of the acquisition of feeds in the community from the FP10 route removes the accompanying regulation and oversight afforded by the NHS Business Service Authority, the Advisory Committee on Borderline Substances (ACBS) and the Drug Tariff, and tends to circumvent the clinical expertise and undermine the relevance of GPs in the field of medical nutrition. In practice, “off FP10” contracts appear to be much less common than the unambiguously lawful “on FP10” counterpart.
- 2.3.20. It is possible that including the price of feed to the community within the specific subject matter of the contract, which is a necessary result of “off FP10” arrangements, has economic benefits because, when decisions are made, it takes accounts of a wider set of relevant information than does current procurement practice. Aspects of the relevant economic trade-offs will therefore be considered below. However, questions concerning the legality of “off FP10” arrangements, and the extent to which they conform to statutory NHS frameworks, are beyond the scope of this report.

2.4. Specific issues arising

- 2.4.1. The procurement arrangements for enteral feeds raise a number of challenges and issues that, ultimately, need to be considered together in the light of a range of economic trade-offs and interactions, some of which are quite complex. As always when dealing with such complexity, there is risk that what appear to be sensible responses to individual issues, each considered on a stand-alone basis, can lead to adverse, unintended consequences for the workings of a wider system of arrangements, which in this case can be taken to the NHS as a whole.
- 2.4.2. Nevertheless, before examining how the various trade-offs interact with one another, it is useful, as a first step, to look at some of the principal aspects of the procurement arrangements one-by-one, remembering always that this is just an intermediate stage in the process of assessment.

‘Follow on’ effects in the typical contract

- 2.4.3. Under the typical contractual purchasing arrangements, for tube fed patients there is a very clear “follow on” effect whereby the supplier who has won the contract for supply of tube feeds to the hospital can expect to see purchases of further feeds via the pharmacy route which arise ‘mechanistically’⁸ from the established

⁸ The abuse of dominance case, *Napp Pharmaceutical Holdings v DG Fair Trade*, explores follow-on effects in the supply of slow release morphine pills, and the extent to which such effects can be thought ‘mechanistic’. The full judgment is available here - <http://www.catribunal.org.uk/237-565/1001-1-1-01-Napp-Pharmaceutical-Holdings-Limited-and-Subsidiaries.html>

practice. This has led to a business model for pricing in which the supplier heavily discounts prices for the purposes of the public contract, in practice to below-cost levels, and relies on margins consequentially earned via the pharmacy route to compensate for the losses implied by the terms of the contract (an assessment of the economic effects of such a pricing model follows in section 3). According to the CMU Guidance, it is common practice for feeds, pumps and plastics to be priced in the contract at a purely nominal price (e.g. 1p per item)⁹, implying that there is near zero recovery of the costs incurred in supplying these items.

- 2.4.4. For ONS patients, the follow on effect is less ‘mechanistic’. As noted above, if patients are initiated within hospital, or receive supplements as they transition from tube feeding, a supplier might expect a significant follow on effect in community sales. However, where patients are initiated in the community, the situation is less clear cut: it can be expected that the secondary sector contractual decision will have some influence on GP prescribing, but to a lesser and more uncertain extent than for tube fed patients.
- 2.4.5. Correctly in our view, therefore, the Guidance identifies a potential follow-on effect, where market shares of ONS in the community increase as a result of contract awards in the secondary sector. This may be due to continuity of care considerations for patients initiated in hospital and/or to a more diffuse ‘hospital influence’¹⁰, occurring for example because GPs have greater knowledge of the products used in a local hospital setting and greater experience of using the relevant products through prescription to transitioning patients.
- 2.4.6. It is to be expected then that suppliers of ONS in the community, as part of their overall commercial strategy, will be able to cross-subsidise¹¹ the products and services which are the subject matter of contracts via the procurement route, by reliance on increased sales of ONS in the community market which follow on from the awarding of contracts in the hospital setting. While the follow on effect is less mechanistic than its equivalent in tube feeds, it is nevertheless a feature of the commercial and economic context and, as such, it can be expected to affect commercial conduct.
- 2.4.7. The Guidance states that contractors cannot assume the existence of this follow on effect¹² during the procurement process:

“... there has been an ‘assumption’ that there would be a ‘follow through’ of feed products and this ‘assumption’ has been used to forecast

⁹ See the Guidance, paras 1.4, 3.22 and Figure 4.

¹⁰ See *Napp* above.

¹¹ That is recover at least some of costs, including a normal commercial return on capital invested, on products or services supplied at below costs, from the revenues generated by other products or services and after deducting the costs, again including a normal commercial return on capital invested, of those other supplies (here ONS).

¹² Para 1.8, p7.

the 'budget' when bidding for the contract. This assumption cannot be made. Contracts awarded for feed products to be used in secondary care cannot influence prescribing in primary care."

- 2.4.8. The difficulty however, is that whilst there is no legal or formal linkage between secondary and primary care decisions, the secondary care decisions do, as a matter of fact, tend to influence primary care prescribing decisions, including for sound medical reasons such as continuity in the feeding regime (which, being taken by the GP, in no way undermine GPs' prescribing freedoms). In the face of this fact, potential suppliers are then bound by their own fiduciary duties to shareholders to take account of the linkages in their search for higher financial returns for their investors.
- 2.4.9. This divergence between what is legally or formally the case and what is economically the case creates an asymmetry between the ways in which the NHS on the one hand and potential suppliers on the other hand evaluate the worth (the value to themselves) of a particular bid. The NHS, constrained by public procurement regulations, is not allowed to evaluate a tender offer on any criteria other than those based on the specific subject matter of the contract. This means that the FP10 price of the feed will not be taken into account by the procuring authority when evaluating the economic merits of the bid. In contrast, suppliers responding to the tenders will take account of the commercial reality of follow-on effects, albeit recognising that they are not 'guaranteed' and that their magnitudes are uncertain. This means that expectations about FP10 prices and volumes will be taken into account in suppliers' assessments of the economic merits of alternative bids.
- 2.4.10. In short, there a basic asymmetry between the ways in which contractors and suppliers tend to assess the value of a contract award. Contractors' perspectives tend to be more focused on implications of decisions for only their own part of the NHS whereas suppliers' perspectives, although also based upon their own organisational interests, are broader and more aligned with a wider NHS perspective *because the procurement decisions will have effects on their revenues not only from the contract, but also from other parts of the NHS (i.e. income from primary sector).*

FP10 Prices – the ACBS

- 2.4.11. Suppliers of medical nutrition products are required to submit an application to the ACBS for a new product to be considered for recommendation to be added to the Drug Tariff. Suppliers submit information to the ACBS on *inter alia*: formulation of the product, including ingredients, nutritional makeup, manufacturing processes and shelf life; evidence of clinical efficacy; and indications and precautions. Within the submission, the supplier includes a

statement of the proposed price to the NHS of a single dispensing unit of the product.

- 2.4.12. This price includes the NHS list price of the product along with all distribution costs that may be typically charged to dispensers.
- 2.4.13. The ACBS will consider the application and, if accepted, will advise that the product be included on its recommended list published as Part XV of the Drug Tariff. Only those products which meet the requirements of the ACBS submission process can be reimbursed by the NHS, unless a GP can objectively justify prescribing a non-ACBS recommended product.
- 2.4.14. Unlike the National Institute for Health and Care Excellence (NICE), which has recently been brought under statute through the Health and Social Care Act 2012, the ACBS has no statutory authority and is understood to act only in advisory capacity for the Department of Health. Additionally, as the products in question are not medicines *per se*, their pricing is not subject to the voluntary Prescription Pricing Regulation Scheme, or to the provisions of the statutory pricing scheme.
- 2.4.15. The process for considering an application for a product to be included within Part XV of the Drug Tariff has three limbs. According to its guidance the ACBS will take account of the ‘clinical need’ for the product, the ‘efficacy’ of the product and the ‘total price to the NHS’.¹³
- 2.4.16. The third limb of the process, the price of the product, is considered under three ‘type’ headings. The first type of product is a ‘new formulation’, the second is formulations which are ‘broadly similar’ to existing products already on the list, and are as such potentially substitutes for those existing products, the third type is existing products for which price changes are proposed.
- 2.4.17. In the information notes on ACBS pricing, there is no indication of how the ACBS might undertake a cost-benefit analysis for the first type (new formulations), for instance what data and evidence the ACBS might consider and how overall it might go about determining whether or not the proposed total price of the new product was acceptable for inclusion of Part XV of the drug tariff. Unlike similar analyses carried out by NICE on, for example, new developments in the treatment of cancer, the ACBS evaluations are not transparent.
- 2.4.18. For the second type (broadly similar products) the ACBS uses a reference price approach for determining whether or not to approve reimbursement for the new product. The applicant indicates the category into which the new product will fit

¹³ See ‘Information Notes on the pricing of ACBS products’, published by the Advisory Committee on Borderline Substances and available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/455113/Pricing_of_ACBS_products_-_August_2015.pdf

and the ACBS will use the benchmark cost of that category of product as a ceiling price for accepting the new submission.

- 2.4.19. For the third type (a pricing change for an existing product) – in contrast to pharmaceutical products where the trend of prices is downward over time as patents expire, new treatments render old ones obsolete, and companies signing up to the Pharmaceutical Price Regulation Scheme (PPRS) negotiate portfolio discounts – medicinal nutrition products prices have tended to increase over time, driven among other things by different cost dynamics. The ACBS therefore encounters many more cases of requests to increase product prices than do comparator bodies dealing with pharmaceutical products. Its general approach in these cases is to benchmark suppliers' proposed price increases against movements in the Retail Price Index, excluding mortgages, over an annual cycle.

Rebates

- 2.4.20. Differences between the 'price determination process' for FP10 prescriptions and for secondary care supplies create what is, from the perspective of the NHS as a whole, a further asymmetry in procurement of enteral feeds, as it also does for pharmaceutical products. FP10 prices are determined nationally – there is a single price throughout England – whereas secondary sector contract prices are determined locally. Hence, potentially at least, contract prices can vary from area to area whereas FP10 prices cannot.
- 2.4.21. Experience drawn from the supply of pharmaceutical medicines indicates that suppliers are often willing to discount their product prices at a local level. Over recent years there has also been some tendency for CCGs and suppliers to have resort to commercial practices characterised by discounts from FP10 prices for primary care supply of feeds in a local area, for example in return for being afforded 'preferred supplier' status in that area. We understand that, whilst this is not currently the norm, the extent of the practice is nevertheless a significant factor in the market.
- 2.4.22. In light of the reimbursement policies and mechanisms of the NHS, the reduction in prices negotiated between suppliers and CCGs typically take the form of retrospective rebates. Because the pharmacy dispenser will always be reimbursed at the NHS list price by NHS Business Services, the supplier transfers money via a side payment to the CCG budget according to the volumes of drugs/medical products dispensed and the reduction in price negotiated.
- 2.4.23. From a GP point of view, which will typically be formed on an 'other things equal' assumption (an individual GP or group of GPs is unlikely to think that their own decisions will have significant impacts on the market as a whole), this practice appears to have the effect of increasing overall prescription budgets in primary care via the payment of the rebate (the validity of the 'other things equal' assumption will be discussed later). From an individual supplier's point of view,

the attraction of the practice lies in the potential for it to be able to discount a product price at a local level in order to enhance its local sales, without having to cut its prices at a national level. The general term for such a practice is targeted discounting.

- 2.4.24. In the specific case of products reimbursed by the NHS, such targeted discounting has a further potential attraction to suppliers operating on an international basis, which is absent in most markets in which the pricing practice occurs. This arises from the fact that the UK Drug Tariff Price is used as a benchmark for determining product prices in a range of overseas jurisdictions. Thus, for example, a pharmaceutical company can offer targeted, retrospective rebates without affecting the list price, and hence avoid any depressing effects that a list price reduction might have on the prices that it can obtain from sales of the same or similar products in other, price-regulated markets. The value of this effect to suppliers is likely much less pronounced for medical nutrition products than for pharmaceuticals, since price determination for the former is influenced more by competitive market factors and less by regulatory practices (such as benchmarked price caps) than is typically the case in pharmaceuticals. Some level of effect may nevertheless be present, although ultimately this is matter for empirical determination.
- 2.4.25. Primary Care Rebate Schemes (“PCRSs”), as they are known, are common across many different products and, given the structure and nature of the NHS, it is understandable that their legality has been subject to scrutiny. As a response to growing demand for clarity on their compatibility with the provisions of, amongst other things, competition law, bribery law, and the statutory scheme for prescription services, the London Procurement Partnership (LPP) has in the recent past sought legal advice on these schemes. The LLP summarised the nature of that advice by way of a statement of “principles”, which has been cited on many CCG websites around the country¹⁴.
- 2.4.26. The top-level message of the legal advice was that primary care rebate schemes were not unlawful *per se*, but that there was a range of practices and protocols that needed to be followed if CCGs wished to be assured that they were not acting unlawfully in the specific, individual context in which they were acting. In relation to the rebate schemes in the enteral feeds market, two of the most relevant guiding principles are:
- i. Schemes encouraging exclusive use of a particular drug should be avoided.
 - ii. Ideally the PCRS should not be directly linked to an increase in the market share or volume of prescribing of the products of a supplier offering a discount.

¹⁴ The advice was given in the context of pharmaceuticals, although we expect the advice to have similar applicability in the context of borderline substances such as enteral feeds.

- 2.4.27. The wording of these principles is notably vague. For example, what does and does not warrant “encouragement”, and should arrangements that can reasonably be expected to lead to an increase in market share or volume – even in the absence of a formal, textual reference to that expectation in an agreement — be counted as giving rise to a direct linkage? Indeed PrescQIPP has created the Pharmaceutical Industry Scheme Governance Review Board to provide further advice and guidance to CCGs on these issues. Consideration of the strict legality of any of the enteral feeds arrangements is beyond the scope of this paper, but the economic issues which arise from volume-based discounts and exclusivity are discussed below.
- 2.4.28. It is also worth noting that, in the more specific context of enteral feeds, these primary care rebate schemes have tended to eventuate within the public procurement contract itself, as opposed to being negotiated separately between CCGs and suppliers, supplementary to FP10 reimbursement. If these arrangements are made within the framework of the typical contract described above, i.e. one in which feeds to the community are expected to be purchased via the pharmacy reimbursement route, any contractual linkage clearly creates a situation where consideration is being given in procurement decisions to product prices that beyond the specific subject matter of the contracts themselves. Under public procurement rules, and according to the Guidance, bids cannot be evaluated on anything beyond that specific subject matter of the contract. It is therefore unclear what place, if any, there is for rebate agreements within procurement contracts that follow an “on FP10” model, at least if current procurement principles are retained.
- 2.4.29. We understand that currently there may be a systemic reluctance for NHS bodies to re-issue invitations to tender upon the expiry of current arrangements. The standard practice at the moment is for contracts to run for 3-5 years with an option to extend the contract by two further twelfth month periods. Nevertheless, there appear to be contracts that continue without re-tender even after the passage of a full 5-7 years has passed¹⁵.
- 2.4.30. There are some obvious possible explanations for the existence of a reluctance to retender which merit further investigation. One is the existence of local rebate schemes: if in the past there has been informal linkage of hospital contracts to rebates on FP10 prices, re-tendering leads to awkward dilemma for the relevant procurement authority. Given the increased scrutiny in relation to legal issues, explicit linkage could be seen as giving rise to risks of legal challenge. On the other hand, full de-linkage of secondary care contracts and FP10 prices in a re-tendered contract risks losing the financial benefits of the rebates secured in an earlier period when less attention might have been paid to good-practice

¹⁵ For example, an exploratory examination of historical procurement exercises suggest certain contracts in, Derbyshire, Hampshire, Leicestershire, Nottinghamshire, Surrey and North Yorkshire have expired with no new tenders.

procurement principles and legal constraints. It is a not unfamiliar behavioural characteristic of decision makers to seek to avoid choosing between relatively unattractive alternatives, if feasible avoidance mechanisms are available. Delay is one such mechanism.

- 2.4.31. Secondly, re-tendering itself implies that some resource costs will be incurred by the NHS in terms not only of the time and money expended on the assessment and decision process itself, but also factors such as the risks of legal challenge in the event that mistakes are made along the way. The existence of such re-tendering costs is one of the factors that should properly have been taken into account at the outset, when tendering arrangements were first introduced. For example, realistic anticipation of significant costs of re-tendering can be expected to lead to recourse to a longer contract duration than might otherwise have been the case if such costs were lower, precisely so as to economise on these resource expenditures. In principle therefore, once the contract route has been chosen and the contract duration specified, re-tendering costs should not be a factor relevant to the timing of re-tendering (which should be determined by the earlier decision). In practice, however, and particularly if resources at the time that re-tendering is due are heavily squeezed, it can be tempting to let any existing arrangements run on.
- 2.4.32. Thirdly, and most probably of greatest importance in practice, existing arrangements for secondary care contracts lead to bids characterised by very low prices, substantially below the actual costs incurred by suppliers, for the relevant products and services. This is because, as discussed above, bidders take account of the financial benefits that will accrue to them from additional primary sector sales in the event that they win the contract (the follow-on effects). In consequence of this bidding behaviour, expenditures on enteral feeds in the secondary sector tend to be very low, implying in turn that, short of bidders offering to provide products and services at negative prices¹⁶ (e.g. actually pay hospitals each time a feed is consumed), the potential financial gains available from re-tendering will appear to be commensurately low, at least when evaluated on the basis of an ‘other things equal’ assumption. The upshot is that, by virtue of the way in which they work, the existing procurement arrangements provide little financial incentive for NHS bodies to re-open the process of competitive bidding. Indeed, even low levels of costs arising from the process itself or from small increases in the risks of other types of costs being incurred (e.g.s. risks to existing FP10 rebates, risks of legal challenge) may be sufficient to eliminate the financial incentives entirely, or to create a situation in which re-tendering would actually result in a net financial loss to the NHS body/bodies engaged in procurement.

¹⁶ In practice negative prices are not a realistic possibility. They would imply that hospitals could increase their income by asking to be supplied with more feeds and then simply throwing them away. More generally, they would be an obvious stimulus to waste and inefficiency in use.

2.4.33. It seems likely in current circumstances, therefore, that those NHS bodies already receiving favourable terms under historic contracts will lack incentives to re-tender in the timely way contemplated by more general procurement policy.

Bundling

2.4.34. As discussed, the public contract awards usually cover the supply of feeds, pumps and some ancillaries in the secondary sector, and supply of equipment, ancillaries and nursing services in the primary sector. Off-FP10 contracts will also include feeds to the primary sector. That is, the contracts cover a 'bundle' of products and services, the precise make-up of which is determined by contractors and which can vary from case to case.

2.4.35. Invitations to tender may separate elements of the supply into lots, opening up the potential for different suppliers to win different elements of the supply. In principle, one company might win a contract to provide feeds and equipment, and another to provide home delivery and nursing. In practice, however, market suppliers tend to operate on the basis of integrated service units, and separation into lots that divided the supply of products from the supply of services could not be expected to lead to more economically advantageous bids to the NHS, at least in the short-term (see below), not least owing to the compatibility issues which arise between equipment and tube feeds.

2.4.36. In terms of the supply of products themselves, it is worth noting that there are well over a thousand different nutritional products currently listed on Part XV of the Drug Tariff. Products are available for the treatment/management of a huge range of metabolic disorders, physical disorders, intolerances, and conditions, with (as noted above) specific and separate formulas for adults, children and infants. As a consequence, when an invitation to tender currently requests provision of feeds in the hospital setting, the bidder will be invited to submit their catalogue of products on offer.

2.4.37. The expectation under the award criteria is that this catalogue will be extensive in its range. Any gaps in the contract winner's supply will result in the hospital needing to purchase products from other suppliers. A successful bid may consequently end up offering to supply competitors' products to hospitals, or offer retrospective discounts against these purchases in order to improve their own bid's evaluation.

2.4.38. This potentially creates a bias against suppliers who only offer specialist nutritional products, who may find it impossible to win contracts with hospitals that 'prefer' bids covering a wide range of medical nutritional products. As indicated above, there are only three suppliers, Nutricia, Abbott and Fresenius Kabi, that are currently in a position to provide all three elements (feeds, equipment, nursing services) typically procured via the tender procedure, but it is notable that there are several other suppliers who currently offer ONS and

specialist nutritional products such as infant formulas, who collectively have a significant share of the market within the community.

Evaluation criteria

- 2.4.39. As explained, the FP10 price of feeds is not a formal consideration when determining the price advantages of arrangements made between consortia of NHS bodies and suppliers via the public contract route. This ‘lack of consideration’ sits alongside a commercial understanding of the reality that there is a clear follow-on effect in tube feeds between the hospital where feeds are acquired by contract, and the community where feeds are acquired by prescription, and a less clear, likely smaller, but nevertheless extant follow-on effect in ONS between hospital and community.
- 2.4.40. As also previously indicated, a consequence of the follow-on effects is that, in competing for contracts, commercial operations can be expected to offer heavy discounts on their offerings and seek to ‘finance’ these discounts from the anticipated, additional community sales. As a result, as identified in the Guidance, product prices offered in tenders have tended towards being ‘nominal’ or even free of charge.
- 2.4.41. When it comes to evaluating the prices under the contract, we understand that a simple formula is typically used to calculate the scores to be given to each bidder based on the prices offered. This formula for calculating the score of any given bidder is as follows:

$$\frac{\textit{Price offered by lowest bidder}}{\textit{Price offered by this bidder}} \times \textit{Maximum Points}$$

- 2.4.42. Suppose that three bidders submitted bids for a contract: Bidder A offered its products for £5,000; Bidder B offered its products for £4,000 and Bidder C offered its products for £6,000. Suppose also the maximum point score available for the price offering is 20. In this situation the points allocation would be as follows.

$$\textit{Bidder A: } \frac{\pounds 4,000}{\pounds 5,000} \times 20 = 16.0$$

$$\textit{Bidder B: } \frac{\pounds 4,000}{\pounds 4,000} \times 20 = 20.0$$

$$\textit{Bidder C: } \frac{\pounds 4,000}{\pounds 6,000} \times 20 = 13.3$$

- 2.4.43. Setting aside other potential problems with this formula which may arise generally in procurement scenarios, consider the implications of the points scoring system in a situation where products are being heavily discounted from

their market value. Suppose that in fact these suppliers were cross-subsidising their costs on the basis that each expected to be able to recoup £20,000 from consequential, incremental sales elsewhere. If this cross-subsidy were eliminated, in this instance the scoring system would look as follows.

$$\text{Bidder A: } \frac{£24,000}{£25,000} \times 20 = 19.2$$

$$\text{Bidder B: } \frac{£24,000}{£24,000} \times 20 = 20.0$$

$$\text{Bidder C: } \frac{£24,000}{£26,000} \times 20 = 18.5$$

- 2.4.44. Though the rank of bidders is still the same, B ahead of A ahead of C, the difference in score is significantly narrower, and in a system in which price scores are being aggregated with quality scores to determine the overall award, differences in quality would be much more likely to play a determining role in the making award if the wider pricing context is explicitly recognised.
- 2.4.45. An example taken to the extreme is a situation in which one supplier offers a 100% discount on its products, that is offers its products for free, and another supplier offers its products for a nominal cost, say a penny. This will result in the first supplier gaining maximum points (twenty), and the second supplier gaining zero points, despite there being a trivial difference in their pricing and only a very small difference in the actual expenditures that would be incurred by the contractor.

3. Economic Assessment

3.1. Salient economic trade-offs

- 3.1.1. Consideration of a number of characteristics of the market for enteral feeds has, in the previous section, led naturally to the identification of a number of economic issues that are relevant in assessing current NHS procurement arrangements. In this section, the preliminary points are linked to more general economic trade-offs that arise across a range of markets and which have been examined in considerable depth in those other contexts, particularly in relation to the conduct of competition and regulatory policies, including in other markets in the health sector.
- 3.1.2. As has been stressed already, the principal focus is on economic matters, not on questions of legality. The two are, however, closely related, particularly in relation to competition law, because legal frameworks themselves tend to be developed and tend to evolve in ways that serve to prevent or mitigate harmful economic conduct whilst permitting economic practices that are beneficial. Thus, for example, a prohibition of abusive conduct by a dominant firm, as in Chapter 2 of the UK Competition Act or Article 102 of the TFEU, is intended to prohibit certain types of harmful behaviour which either have the effect of impeding competition or damaging the interests of consumers (in enteral feeds a term that can be broadened to encompass procurement authorities making purchases to meet the needs of patients) or both. Roughly, it might be said that market abuse amounts to behaving in ways that are anti-competitive or that harm consumers. This particular provision of competition law is therefore very closely aligned with a specific public policy purpose.
- 3.1.3. The economic focus in this report is on those potential effects of current procurement arrangements that give rise to risks of one or both of these two types of harm (harm to competition, harm to consumers). Whether or not any resulting harms are sufficiently large or are likely to satisfy the precise conditions required for the application of competition law in a given context is a question that will not itself be addressed.

Complementarities in demand

A. Follow on effects

- 3.1.4. As discussed, a central feature of the economic context is the existence of ‘follow on’ effects whereby purchasing decisions in the secondary sector have material implications for the demand for products and services in the primary sector. Specifically, the award of a contract to supply a contractor in the secondary sector, where the initiation of patient use of enteral tube feeds tends to be concentrated, leads to increased demand for the same suppliers’ products when the patient is transferred to primary care.

- 3.1.5. In economic terminology, follow-on effects are a type of complementarity in demand. Such complementarities are defined as demand linkages that have the feature that a reduction in the price of one product or service *increases* demand for a second product or service, assuming no change in the price of the latter¹⁷. When this condition is satisfied it is also usually the case that other (non-price) factors that cause an expansion in demand for one product, such as increased marketing expenditure or an improvement in product quality, also cause an expansion in demand for the other. A familiar example of such complementarity is to be found in games consoles (Playstation, Xbox) and games software. A lower price of consoles will lead to higher levels of machine ownership and hence to a larger customer base to which software suppliers will be able to sell their products (i.e. to higher demand for software).
- 3.1.6. Whilst the existence of demand complementarities is a familiar feature of economic life, as the games console/software example illustrates, the position in the enteral feeds market is slightly unusual, and this can be a source of confusion. In the normal case the complementary products are usually different in physical and functional ways (e.g.s. consoles and software, cups and saucers, microwave ovens and ready meals). When products and services are broadly similar in physical or functional terms, they are most usually substitutes for one another.
- 3.1.7. Substitute products and services are defined by the condition that a reduction in the price of one product or service leads to a reduction in the demand for another. Thus, Coca Cola and Pepsi Cola are demand substitutes, since a reduction in the price of one will lower demand for the other, assuming that the other continues to be sold at the same price as before. This is because some consumers will switch their purchases to the product or service that has, by hypothesis, become cheaper relative to the other.
- 3.1.8. The differentiation in the enteral feeds context comes not from physical or functional differences in the products, but rather derives from the differentiated procurement arrangements within the NHS. In economic terminology again, the structure of these arrangements serves to ‘segment’ the market. A corollary of this point is that the scope and magnitude of follow-on effects is a function of the procurement arrangements themselves. The latter are only a contextual ‘given’ (like the distinction between games consoles and software), if it is assumed that the arrangements themselves are a given, and this is a crucially important point to which we will return later.
- 3.1.9. Follow-on effects featured heavily in the Napp Pharmaceuticals decision and in that case, which was concerned with the supply of sustained release morphine capsules and tablets, Napp offered discounts of over 90% on list prices to

¹⁷ If the demand for product A is expressed as $Q_A(P_A, P_B)$, where P_A is the price of A, P_B is the price of a related product B, and the symbol Δ signifies ‘a small change in’, complementary products are characterised by the condition that $\Delta Q_A / \Delta P_B < 0$.

hospitals. These much lower prices in the secondary sector (compared with the primary sector) were found to be unlawfully anti-competitive on the basis that the pricing structure gave rise to significant barriers to entry into the market.

- 3.1.10. The factual position in enteral feeds differs significantly from that in Napp, most notably in that none of the existing suppliers has a share of national sales anywhere near as large as that of *Napp*. Nevertheless, the underlying causes of the highly asymmetric (as between secondary and primary sectors) pricing structures are the same: features of the market that give rise to follow-on effects.
- 3.1.11. Given that the precise ways in which secondary-sector procurement arrangements are specified are themselves capable of affecting the magnitudes of follow-on effects, and hence of affecting the wider implications of those effects for the ‘whole health economy’ (the expression used in the Guidance for the wider NHS interests), our view is that the Napp case points to the conclusion that secondary sector decision makers should, when developing tenders and when assessing the economic advantages of competing suppliers’ offers, give some consideration and weight to the potential effects of their activities and decisions on competitive conditions.
- 3.1.12. We note that such assessment of effects on competition appears to be absent in both tendering activities themselves and in the Guidance issued in relation to the specification of tenders. The matter is important because procurement processes that have the effect of weakening competition may give rise to a situation in which procurement authorities will have less choice and face higher prices in future re-tenders. And, of course, there can be more direct questions concerning the extent to which tendering activities comply with competition law more generally (see for example the issues raised in the London Procurement Partnership Guidance for CCGs discussed below).

B. Suppliers’ product offerings and pricing

- 3.1.13. The second, major aspect of demand complementarity that is relevant in assessing procurement arrangements, at least in a tube-feeding context, arises from the distinctions between the feeds themselves, the ancillary equipment used in consuming them (pumps, tubes, etc.) and the distribution/delivery and nursing services that go along with their consumption. These different things tend to be consumed ‘together’ in a sense that is similar to that implied when talking about games consoles and software.
- 3.1.14. Since there can also be significant supply-side complementarities associated with these different products and services (see below), the demand-side issues are better considered in the more general discussion of the next sub-section.

Suppliers' product offerings and pricing

- 3.1.15. A supplier serving customers in both the primary and secondary sectors will naturally take account of demand side complementarities when determining its commercial conduct. Investors are interested in overall financial returns on their invested capital and it is on these that directors, in order to fulfil their fiduciary duties, necessarily have to focus. If, say, a pricing or marketing decision in relation to supplies to the secondary sector would have likely implications for revenues drawn from the primary sector, this fact will be taken into account when evaluating alternative pricing options. What matters to the business in the end is total revenue less total cost, and total revenue will be the sum of the primary sector revenue and the secondary sector revenue.
- 3.1.16. Another way of looking at this is to say that, when evaluating a potential secondary-sector contract, a supplier will necessarily recognise (and take into account in its decision making) the fact that the contract has potential value additional to the revenues directly associated with the secondary sector supplies themselves. This additional value equates to the net revenues (revenues less costs) arising from any 'follow on' effects on business in the primary sector. Suppliers will therefore (necessarily) approach secondary sector contracts in a 'holistic' way based on their potential contribution to overall (primary and secondary sector) profitability, not just their secondary sector revenues and costs.
- 3.1.17. In these circumstances, the general tendency in commercial pricing is to discount prices to secondary sector customers relative to the prices that would be set if suppliers marketed their products only in the secondary sector. A supplier serving only the secondary sector would seek to offer prices that maximised its net revenues (revenues less costs) from secondary-sector sales, whereas a supplier serving both sectors would recognise that additional sales to the secondary sector would generate additional benefits from the same business's primary sector activities. It is therefore worth discounting secondary-sector prices to at least some degree (i.e. give up some returns from secondary sector sales) in order to capture some of this additional value.
- 3.1.18. This type of discounting based on anticipated returns from follow-on sales is not problematic by and of itself, although, as the Napp case illustrates, it can cause problems in some types of context (e.g. when, as in Napp) there is a dominant firm). Supermarkets, for example, may offer very keen prices on sales of petrol at co-located facilities or on a number of prominent 'key value items' (KVIs) in order to attract customers to a site in the hope or expectation that they will then purchase other products whilst there (the 'follow-on' sales). There is no obvious detriment to consumers in this, provided only that the practice does not lead to elevated prices for the overall shopping basket. The matter has been explored by the Competition Commission, which has found that such detriments are absent in consequence of competition among supermarkets: if the consumer experiences a

poor deal on the overall shopping basket, he/she will simply switch to a different retailer.

3.1.19. Similar points apply to the relationships between enteral feeds and ancillary products and services: what matters to the buyer is the cost of satisfying the overall purchasing requirements. Where products and services are strongly complementary they are often supplied together in a bundle or package, via a single transaction or contract. Two reasons for this are:

- i. There are cost advantages to the suppliers in doing things this way. This is the ‘cost complementarity’ referred to above: if a company supplies one product or service, it may be able to supply other products at lower prices than would be the case if those other products were supplied on a stand-alone basis. The source of the cost reductions may lie in production, distribution or sales and marketing, depending on the particular economic context. An illustration is satnav equipment in modern cars: it now tends to be cheaper to build the equipment into the vehicle at the manufacturing stage than to supply it as an ad-on at a later stage.
- ii. There can be transactions cost advantages in buying/selling a bundle of products/services rather than buying/selling the various components separately. Buyers in particular often find it convenient to transact in this way, and this is a fundamental factor in, for example, the grocery sector: supermarkets aggregate large numbers of products at one location, thereby reducing shopping costs for the consumer.

3.1.20. Again, there is nothing that is problematic in product bundling per se, and it only tends to become a concern when competition for the buyer’s business is weak and bundling may have the effect of sustaining restrictions of competition, for example by impeding innovations that might be offered by new competitors who seek to supply only one or a limited number of components of the overall bundle.

3.1.21. This can be an issue in relation to the supply of on-patent pharmaceutical products in cases where patent protection affords a significant degree of market power, as illustrated in the Genzyme case. Enteral feeds do not, however, fit into this category and the application of normal competition law standards should be more straightforward. These indicate that product/service bundling is only likely to pose public policy issues in the presence of (a) market dominance by an individual supplier or (b) ‘horizontal’ agreements between competing suppliers (e.g. a supply cartel).

Bidding markets

3.1.22. In markets in which a large commercial or governmental organisation is the relevant buyer, it is not uncommon for their requirements to be put out to tender. That is, a particular project or a particular sequence of purchases are made subject

to a contract for which competing suppliers are asked to bid. The supply of enteral feeds to the secondary sector is dominated by this type of commercial arrangement.

- 3.1.23. In such ‘bidding markets’, the economics literature indicates that the way in which tenders are specified is a matter of some considerable importance, and one of the most frequently observed pitfalls into which procurement policies can fall arises from the view that existing competition among suppliers will provide full protection against the consequences of inappropriate specification of tenders. One reason why this view is mistaken is that contract specification can itself affect competitive conditions over time.
- 3.1.24. Consider, for example, a situation in which a buyer chooses to meet all requirements from a single supplier: a ‘winner takes all’ contest. This can have advantages in terms of convenience for the buyer and lower costs for suppliers. When such a ‘requirements contract’ is first awarded, there may be strong competition among alternative suppliers such that the cost advantages are passed through to the buyer in the form of lower prices. However, having obtained the contract, subsequently made investments that may be specific to the particular buyer, and having established commercial relationships with the buyer, the winning bidder may find that, in bidding for subsequent contracts, it has significant commercial advantages over its rivals (these are sometimes referred to as ‘incumbency advantages’). Indeed, recognising this fact, some of the potential rivals may devote less time and effort to the later contests, because the tendering process imposes costs on suppliers and the prospects of success may be perceived to be slim. In the worst case, these potential rivals may simply not bid at all.
- 3.1.25. This is, in fact, a recurring empirical pattern: early tenders are highly competitive and deliver cost savings, but competition for subsequent tenders diminishes over time and prices rise, to the longer-term detriment of the buyer. This chilling of competition over time can, however, be avoided by multi-sourcing on the part of buyers, a practice that is widely adopted in the commercial sphere. Thus, rather than award all business covered by a tender to a single supplier, the buyer can choose to split the business between two or more suppliers. Then, even though a favoured bidder might be awarded the lion’s share of the business, there will be ongoing relationships with other suppliers who might be induced to compete more vigorously for an expansion in their share of purchases in subsequent tender rounds.
- 3.1.26. There are numerous examples that could be cited at this point, but supply of computers by ‘original equipment manufacturers’ (OEMs) is a good illustration of the phenomenon. Computers require central processing units (CPUs) and in the recent period Intel has been the dominant supplier of CPUs for desktops and laptops. The major OEMs have, however, tended to multi-source (Dell initially operated an Intel-only policy, but later abandoned it). One reason for this is that

the relevant CPUs have differentiating characteristics that are favoured differently by different groups of end consumers, but another is that it enables the OEMs to sustain a higher level of competition for their business over time. If the major OEMs had adopted a ‘winner takes all’ approach to sourcing their CPU requirements, the likely consequence is that AMD, Intel’s only major competitor, would have gone out of business long ago. Indeed, it may not have entered the market in the first place.

- 3.1.27. Again, in our examination of documents relating to NHS secondary sector procurement, we find no strong evidence of a recognition that today’s ways of doing things can have significant effects on the opportunities for cost reduction and service enhancements in later periods. Longer term perspectives seem to be lacking.

3.2. Economic Assessment of Competition

- 3.2.1. Formal economic assessments of competitive conditions are playing an increasingly important role in the health sector and in addition to the work of Monitor in this area a number of ‘mainstream’ competition law cases have been focused on issues that are of direct relevance to the supply of enteral feeds, Napp and Genzyme being major examples. Three issues that have emerged in these more general developments appear to be of particular relevance in the current context: market definition, exclusive purchasing and (to a lesser extent) volumetric pricing.

Market definition

- 3.2.2. In order to calculate the market shares of sellers and buyers it is first necessary to identify what is meant by the relevant market, and in practice this can be an area of considerable, and often unnecessary, controversy. In fact, formal market definition is simply a classification exercise, based on deciding which products and services are to be counted as being ‘in the market’ and which products and services are to be counted as being ‘outside the market’ (product market definition), over what geographic area the market extends (geographic market definition) and, occasionally, what time periods are relevant (in rail services, for example, peak and off-peak travel might be distinguished).
- 3.2.3. Whatever classification is made the underlying economic reality remains the same. A sound assessment of competitive conditions – which is focused on the alternatives or substitution options available to buyers and sellers – should, therefore, arrive at the same conclusions no matter what classification is adopted. Unfortunately, competition policy assessments sometimes violate this invariance condition and it is this failure that leads to unnecessary controversy.
- 3.2.4. A corollary of the invariance proposition is that the substantive economic value to be derived from the market definition exercise lies in the collection and

assessment of information relating to the ready availability of alternative counterparties for both buyers and sellers, i.e. relating the degree of substitutability in the market, on both the demand side and the supply side. It is generally advisable, therefore, to concentrate on the question of ‘alternatives’ from the outset. A good market definition (i.e. good classification scheme) will then be one that reflects the alternatives available to those engaged in the relevant transactions.

- 3.2.5. There are a number of dimensions of the market definition exercise, but in enteral feeds the most important of these appears to be to do with geography: should the market(s) be defined as being national or local in scope? We therefore focus chiefly on this issue whilst noting that there are other aspects that would need to be considered in a fuller analysis, including whether or not ancillary equipment, home delivery and nursing services should be counted as integral features of the ‘product’ or should be considered as distinct markets in themselves.
- 3.2.6. For suppliers of enteral feeds alternative buyers can be found nationally and indeed internationally: the relevant companies are not specialised in serving a particular locality. A similar point applies in relation to buyers: procurement authorities are not significantly restricted in their choice of supplier by their particular location. These features point, *prima facie*, toward a geographic market that is national in scope.
- 3.2.7. There is, however, an obvious difficulty in adopting a national market definition when the issue is considered in the specific context of NHS procurement. Competition policy places heavy emphasis on the interests of ‘end’ consumers who in this case are the end users of the relevant goods and services, i.e. the patients. The NHS arrangements imply that procurement authorities make decisions on behalf of geographic aggregations of patients and hence that, once those decisions are made, individual end consumers have a relatively restricted range of choices available to them (unless they bypass the NHS system entirely, which relatively few do). If for example, a local CCG makes a purchasing decision, that decision will have similar implications for all patients in its home area. Patients themselves do not make unconstrained choices on an individual by individual basis: their alternatives are *de facto* restricted by geography, and this is a fact of the context that cannot reasonably be ignored.
- 3.2.8. The point here is not decisive in relation to market definition in general: purchasers of petrol for cars or of groceries for home consumption are also constrained by their locations to some extent yet in competition law cases the relevant markets have often been defined as being national in scope. In these latter situations, however, there is often a set of factual, contextual considerations that lead to the final conclusions. For example, a dispersed population coupled with at least some degree of geographic mobility may mean that hard and fast geographic boundaries are not easily identified and that prices in adjacent areas

have constraining effects on prices on each other. For example, it may be fairly easy to drive across a purely notional boundary if good deals are on offer on the other side, or it may simply be the case that suppliers are observed to set their prices on a national basis so that more localised effects are absent.

- 3.2.9. For enteral feeds the NHS secondary care procurement arrangements imply that the geographic boundaries are much clearer than, say, in retail petrol or grocery markets being defined by NHS structures and contractual processes themselves; and where patients receive secondary care away from their home (primary care) area, the significant factors determining that particular choice will not typically include the prices and service quality of enteral feeding. In economic terms, significant geographic substitutability in demand is largely absent.
- 3.2.10. When enteral feeds (or any other products) are procured in the primary sector on an FP10 basis, the economic effects of this lack of geographic substitutability are suppressed as a matter of policy by the Drug Tariff, which is established as a national price list. Even in the primary sector, however, geographic segmentation is introduced when CCGs seek to procure the relevant products and services on a collective basis at non Drug Tariff prices, i.e. via the off-script model.
- 3.2.11. For the moment, the operative conclusion is simply that NHS procurement, as it currently operates, has the effect of introducing geographic segmentation into the determination of prices. In thinking about the consequences of this point, it is important to stress that we are not in this assessment concerned with the question of whether this is a good or bad thing in policy terms: rather, we are simply making a factual observation about how things stand under current arrangements. Geographic segmentation is simply a feature of the context that cannot be ignored in any competition assessment, because it can be expected to affect how competition functions and hence to affect the outcomes to which competition will tend to lead.
- 3.2.12. On this basis, our preliminary conclusion is that a market definition that best reflects factual realities is one that views matters in terms of a set of local markets for enteral feeds in secondary care (matters can be left more open in relation to primary care, where the position is complicated by the simultaneous presence of FP10 and off-FP10 arrangements). Such a market definition helps ensure that the implications of geographic market segmentation are given due weight when assessing the economic effects of current procurement arrangements.
- 3.2.13. For the reasons given, sound economic assessment is invariant to market definition. In the alternative it is possible to define a national market for enteral feeding products and services by the contract route. However, greater care and attention is then needed to ensure that there is clear recognition of the geographic segmentation that is created by the procurement arrangements, coupled with careful assessment of its implications. Experience indicates that, if segmentation

is not clearly identified at the outset, in the way that policy issues are first framed, errors in assessment of competition are more likely to occur, which are associated with an underweighting of the significance of geography.

Exclusive purchasing

- 3.2.14. Current procurement arrangements for enteral feeds in the secondary sector approximate to a form of exclusive purchasing by the procurement authority for the duration of the contract. They can be reasonably be described as ‘near-exclusive’ and, in the enforcement of competition law, they would highly likely be approached in the same way as fully exclusive contracts. This reflects the economic reality that near-exclusive purchasing arrangements typically have similar economic effects on competition and market outcomes as full exclusivity.
- 3.2.15. Given the geographic segmentation induced by current procurement arrangements, such CCG ‘exclusivity’ translates into market exclusivity (if a narrow geographic market definition is adopted) or into exclusivity across a significant segment of the market (if a national market is defined). Either way, the exclusive or near-exclusive nature of the contracts is potentially problematic.
- 3.2.16. Speaking generally, exclusive purchasing arrangements can fall foul of UK and EU competition law under both of its limbs (concerned respectively with anti-competitive agreements and with abuse of dominance). The common element in both limbs is the potential harm that such contracts can have on competition and on consumers.
- 3.2.17. Whilst we are not concerned here with issues of strict legality, the principles underlying the relevant competition legislation are foundation stones of much public policy, across the economy generally as well as in the health sector, and across the EU as well as the UK. Particularly given the prevalence of near-exclusive arrangements in the secondary sector procurement of enteral feeds and the manifestly thorny issues that have arisen in relation to PCRSs more generally, a short discussion of those principles is merited.
- 3.2.18. In summary form, the principal, potential problems that can arise from exclusive contracting, and which give rise to competition policy interventions when it becomes prevalent in a market, are as follows:
 - The buyer’s procurement choices for the duration of the contract are restricted. In most contexts this is generally regarded as unproblematic if, at the time of entering into the contract, the buyer has sufficient other options available and an adequate appreciation of the longer term implications of current decisions. The first condition has almost certainly been satisfied in secondary sector procurement of enteral feeds at the time of entering into the first such contract. Whether it will be satisfied for subsequent contracts is much less clear, for the reasons discussed in the section on ‘bidding markets’

above, i.e. ‘winner takes all (or nearly all)’ contests can have the effect of reducing the number of contestants over time. In relation to the second question (recognition of longer term consequences) there is much more reason to doubt that it is currently satisfied. From the material we have seen, there seems to be little or no assessment of these effects: attention appears to be very much focused on the short-term implications of alternative decisions. This bias to short-termism is likely a function of the way in which the NHS is organised and structured and of the incentives to which these things give rise, raising issues that go far beyond the supply of enteral feeds.

- Competition among suppliers for the buyer’s business is restricted for the duration of the contract. Again, this matters little if suppliers have sufficient other options (to sell) available to them, but it becomes potentially problematic if the exclusivity arrangements cover a large fraction of the potential business available to a supplier, as they do for the supply enteral feeds. Even then, the effects might not be an issue if contracts are frequently re-tendered, since the exclusionary effects are of short duration and opportunities to compete are refreshed frequently (although see the earlier remarks on incumbency advantages). However, five years or more is a relatively long time period for suppliers to be denied a chance to compete for significant business. When such exclusionary effects eventuate they are generally referred to as market foreclosure.
- The potentially harmful effects of exclusion tend to increase (a) the longer the duration of the contracts and (b) the larger the share of business they account for in the relevant market or market segment.
- Harmful effects can also eventuate in related markets or market segments, i.e. markets that are economically linked (though not necessarily legally or contractually linked) to the relevant, defined market. In enteral feeds for example, if supply of tube feeds to the secondary sector were defined as a distinct relevant market, the supply of such feeds to the primary sector would be considered to be a related market, by virtue of follow-on effects. ONS feeds could also be judged to be a related market, although the linkages in this second case are likely significantly weaker.
- The general issues are complicated in the health sector by the separation between (a) the buyer who makes the decisions and (b) the end consumer/patient on whose behalf those decisions are made. The additional complexities have been recognised in health sector cases in UK competition law, as for example when the general presumption that a large buyer such as the NHS can itself exert substantial market/bargaining power has been set aside on account of limitations imposed by the structural organisation of the NHS. In economic terms, in the NHS there is a major principal-agent

problem that needs to be addressed¹⁸, which, in a fuller analysis, would require account to be taken of the linkages to the (taxpayer) funding mechanism and the stewardship thereof (via the political system).

- There can be potential benefits to both contracting parties if exclusivity leads to economies of scale, economies of scope, or lower transactions costs (e.g. lower costs in the administration of procurement), which is why they are generally considered to be benign when identifiable competition problems are absent. Assessments should therefore properly consider the likely magnitudes of these effects, which can differ considerably from product to product.
- Immediately lower prices are not *per se* a clear indicator of potential benefits to buyers. The reason for this is simple: if exclusive dealing has the effect of restricting competition in supply, the increased market power will be a source of financial benefit to a supplier for which the supplier will be willing to ‘pay’, e.g. by offering lower initial prices than would otherwise be the case. A particular buyer might benefit in the short term, but would then lose out later in consequence of diminished competition. This is what happens when pricing is ‘predatory’ and it is why predatory pricing by a dominant supplier is prohibited, notwithstanding that it makes low prices available to consumers in the short term. Indeed, when predation is being practiced, the lower are the short-term prices the higher is likely to be the longer-term harm.
- Moreover, where the harm occurs principally in a related market, it may be immediate rather than delayed. One buyer might benefit from low prices, even in the longer term, but at the expense of other buyers in a related market who suffer in consequence of market foreclosure effects, e.g. because some suppliers or potential suppliers are eliminated from that market. If the supplier is willing to ‘pay’ for the extra market power by offering particularly low prices for a period, it can reasonably be inferred that the losing buyers will tend to suffer more than winning buyers will benefit, so that buyers in aggregate are harmed. In enteral feeds there is therefore a question to be addressed as to whether market foreclosure effects induced, say, by contracting practices for tube-feeds to the secondary sector give rise to harmful effects, such as higher prices, in related primary care and ONS markets or market segments.

¹⁸ Notwithstanding best efforts, the interests of taxpayers, procurement agencies and patients are not co-incident and cannot ever be so in a system based on budgeted allocations of scarce resources. The best that can be done is to eliminate the most egregious of the conflicts of interest and to seek as great a degree of alignment of interests as is realistically possible in the circumstances (‘principal-agent analysis’ is focused on these challenges).

- 3.2.19. It only remains to add that near-exclusive arrangements are prevalent in NHS contractual procurement of enteral feeds and that the fact that this prevalence has developed in consequence of procurement decisions by the buyer, not (as is more usual in other markets) by sellers, does not disturb any of the above points, which are concerned with the economic *effects* of this type of business practice.

Volumetric pricing

- 3.2.20. Volumetric pricing occurs when the supply arrangements are such that the prices paid to a supplier fall as the volume purchased rises, in a way that is typically set out in a pricing schedule. For example, increasing discounts may be offered for purchases in excess of each of a sequence of defined volume thresholds. From the material we have seen this does not appear to be a major issue in the supply of enteral feeds: in secondary care the issues are much more to do with the fact that prices are generally below cost, in primary care the dominant arrangement is characterized by fixed national pricing in which volumetric issues do not arise. Nevertheless, the possibility is considered briefly here because (a) the practice is noted and warned against in the London Procurement Partnership Guidance for CCGs in relation to (non-traditional) primary care rebate schemes for pharmaceutical products and (b) it might become a potential problem as procurement arrangements evolve.
- 3.2.21. The trade-offs are much the same as for exclusive dealing. There are potential advantages of volumetric pricing if there are economies of scale and/or scope in supplying a procurement authority and if the pricing schedule effectively signals these things to the buyer and enables the buyer to reap some of the benefits from the achievement of such efficiencies. Problems only tend to arise when the pricing incentives lead toward monopolisation of supplies (i.e. toward enduring *de facto* exclusivity or an approximation to it) and when the pricing schedule itself reflects anticipated market power effects as well as supply costs, as for example when particularly large discounts for high volumes of purchases are offered and when those discounts do not reflect any underlying cost savings that can be attributed to the extra volume. Any lack of cost-reflectivity may be particularly transparent when contracts link price discounts to ‘share of the buyer’s business’, since it can be expected that a suppliers costs will be linked to volumes but not, at any given volume, to ‘share of business’. Unsurprisingly, therefore, the LPPG Guidance specifically urges caution in relation to ‘share of business’ clauses in contracts.
- 3.2.22. The underlying principle in all this is that market/monopoly power should not be bought and sold. In the language of American antitrust, competition should be ‘on the merits’. In particular, care should be taken by public officials not to unnecessarily create sources of economic rents (payments in excess of what is required to induce requisite supply). Even though there may still be competition for such rents, it is not effective competition or ‘competition on the merits’.

Effective or meritorious competition is rather competition in which suppliers rewards are correlated with the benefits they create for end consumers.

3.3. Evaluation of bids

- 3.3.1. In broad terms evaluation of suppliers' tenders requires assessment of the value of the relevant products and services to the NHS less the costs of procuring them, which we will refer to as the 'underlying evaluation criterion'. Value to the NHS will depend upon both the quantity, quality and suitability of the products and services offered (the notions of quality and suitability here encompass, but also extend beyond, the clinical considerations that are of such high salience in a health sector context). For obvious reasons, such value is frequently very difficult to measure or estimate with any degree of quantitative precision.
- 3.3.2. In practice, matters are simplified somewhat in that what is required is an evaluation not of value *per se*, but rather of the comparative values of competing offers. It is therefore not necessary to estimate value itself, only whether one option is more or less valuable than another when the two are compared. Even so, the exercise is not straightforward.
- 3.3.3. The standard way in which the procurement arrangements operate, which is consistent with at least some practices in public procurement more generally, is to disaggregate value into a number of components, each of which is assessed individually according to a point-scoring system. The points are then aggregated into an overall score according to a weighting system that reflects the perceived significance of the individual components. For example, if value depended on two dimensions of quality, $V = V(Q_1, Q_2)$, this is implicitly measured in the points system by $V = W_1S_1 + W_2S_2$, where W indicates the weight given to the component and S to its score.
- 3.3.4. Good assessment therefore depends upon both (a) determining appropriate weights and (b) determining appropriate scores for the individual cases. This is because, when comparing two offers, the differences in weights and the differences in scores each affect the resulting, aggregated score (which is intended to lead to a reasonable estimate of the difference in overall values of competing bids).
- 3.3.5. The same point applies when comparing the contributions of value-of-product/service differences and price differences between the offers of competing suppliers. The weightings and scoring methodologies must be such that, taken together, they produce a difference in aggregate scores that is at least ordinally related to the underlying evaluation criterion (see further below).
- 3.3.6. To illustrate, consider for simplicity a case in which there is just one quality dimension and one price. What matters to the NHS is $V(Q) - P$, the value of what is provided, translated into monetary terms, less its costs. Consider two offers, the

first (A) with higher quality and the second (B) with a lower price. The first bid is preferable if:

$$V(Q_A) - P_A > V(Q_B) - P_B.$$

Similarly, the second bid is preferable if:

$$V(Q_A) - P_A < V(Q_B) - P_B.$$

In the case of equality between the expressions, there is indifference between the offers: each is as good as, but not better than, the other.

- 3.3.7. A good evaluation procedure will mirror these relationships. Let scores for quality and price be SQ and SP respectively, and the quality and price weights be WQ and WP. Since higher points are awarded for lower prices, to do so optimally it is required that:

$$WQ.SQ_A + WP.SP_A > WQ.SQ_B + WP.SP_B \text{ iff}^{19} V(Q_A) - P_A > V(Q_B) - P_B$$

$$WQ.SQ_A + WP.SP_A < WQ.SQ_B + WP.SP_B \text{ iff } V(Q_A) - P_A < V(Q_B) - P_B, \text{ and}$$

$$WQ.SQ_A + WP.SP_A = WQ.SQ_B + WP.SP_B \text{ iff } V(Q_A) - P_A = V(Q_B) - P_B .$$

- 3.3.8. These relationships make it clear that both the weightings and the scoring methodology for individual components of the tender need to be appropriate when taken in conjunction with each other. Weaknesses in either can lead to poor procurement decisions.
- 3.3.9. The point here is a general one, applicable to all weights-based, numerical scoring approaches to procurement. There are, however, features of the enteral feeds context that serve to aggravate the general measurement problem, of which three appear to be of particular significance.

Lack of recognition of the interactions between determinations of weights and scoring methodologies

- 3.3.10. As indicated, choices about the weighting of components and about scoring methodologies for the individual components jointly determine whether the scoring system as a whole leads to measures that reflect the underlying values and costs of products and services to the NHS. However, the documents that we have read do not appear to show any very clear recognition of this reality: the weights and scoring systems appear to be determined independently of each other, not in combination.

¹⁹ If and only if.

- 3.3.11. Indeed, the CMU’s procurement guidance itself appears not yet to have grappled with the issues. One of the “golden rules” that it sets out is:

The pricing element of the tender should represent no more than 20% of the evaluation weighting.

- 3.3.12. The intention here is clear – to give significantly greater priority to clinical effectiveness than to commercial considerations – but constraining weightings alone does not necessarily achieve that purpose because it can be undone by inappropriate scoring approaches for the individual components of an offer.
- 3.3.13. To illustrate how things might go wrong, consider a scoring system that, in relation to price, awards maximum points to the lower of two prices bid (it being assumed that there are only two offers) and zero points to the higher (we have already given an example of this earlier, which can eventuate from a methodology that has been commonly adopted in practice). This uses the full range of the points scale. In contrast, given that more subjective judgmental procedures are typically adopted for non-price aspects of the bid, there might be a tendency for points awarded to fall in a more compressed range of the potential scale, with very high and very low scores being exceptional events.
- 3.3.14. This is an assessment bias that is perhaps most familiar in student examinations where final rankings are based on an aggregation of marks across more technical papers, characterised by right and wrong answers, and papers that are essay based. In both cases the judgments might rank students in the right order on a paper-by-paper basis, but they can be biased (in terms of overall rankings) toward students who are very good in the technical papers and they are biased against students who are very poor in the technical papers.
- 3.3.15. It is, therefore, not enough that the scoring methodologies for individual components of tenders are ordinally sound, i.e. that the points ranking accurately reflects the merits of the offers on a component by component basis, there also has to be an appropriate relationship between the points differences scored for different components and the weightings given to those scores, if the aggregated scores are themselves to be ordinally sound. Moreover, simply affording a higher weight to factors that are *de facto* scored according to a more compressed points scale does not fully resolve the problem, although it can help. In student examinations with large numbers of candidates this could be done via some form of ‘normalisation’ of within-paper scores, but unfortunately this relatively simple procedure is likely unavailable in tender evaluations for enteral feeds on account of the small number of competing offers.

Neglect of related market effects: the challenges posed by ‘co-ordinated decentralisation’

- 3.3.16. An issue of more specific relevance to the supply of enteral feeds is the existence of economic effects in related markets (or market segments). The CMU’s

Guidance for procurement of nutrition supply services lays some stress on the desirability of a “whole health economy” approach and, among other things, this implies that effects on products, services and markets that are related to (i.e. are affected by) decisions about procurement of a more narrowly defined set of products and services should, one way or another, be taken into account when making those decisions (and indeed also at an earlier stage, when setting up the procurement processes themselves).

- 3.3.17. Thus, the second of the Guidance’s “golden rules” pertaining to understanding the relevant financial context (Section 1) is:

Agree and ensure a whole health economy approach.

A little later in the document, at 1.11, it is said that:

This complex procurement model has led to inequality in the distribution of costs across primary and secondary care. It is essential that the relevant stakeholders from both sectors are involved with the procurement process and have a clear understanding of the costs and benefits of the contract. A whole health economy approach must be considered.

Taking account of likely economic consequences of procurement models and decisions in related markets (and market segments) is clearly one aspect of such an approach.

- 3.3.18. The earlier example of bias in the scoring of prices offered by competing tenders showed how neglect of follow-on effects can lead to poor decisions, because it takes account only of the implications of those offers for contracted products and services, ignoring the consequential effects on NHS costs in related areas of activity. There are, however, significant challenges to be met if such biases are to be eliminated and they raise some fundamental issues about the organisation of the NHS itself.
- 3.3.19. To explain, there is great potential merit in a decentralised ‘division of labour’ in economic decision making, as set out in the opening section of Adam Smith’s Wealth of Nations. In market systems this fragmentation in decision making – which contributes to higher productivity and innovation – is reconciled with requirements for co-ordination in economic life by the competitive market system itself, based on voluntary trading of goods and services within a defined set of generic rules (‘the rules’). To put things simply, the ‘rules’ or ‘institutions’ of everyday economic life, developed over a period of centuries, provide the co-ordinating mechanisms that allow decentralisation of individual decisions to be effective.
- 3.3.20. In more ‘organised’ economic systems such as the NHS, the voluntary trading mechanism is either entirely absent or, when it is first being established, tends to

lack a bedded-down system of co-ordinating mechanisms, since it is generally much easier to delegate/decentralise a particular set of decisions than it is to develop the shared system of rules that serve to ensure that the various individual decisions will, together, lead to better outcomes.

- 3.3.21. In technical economics terminology, organised systems that seek to decentralise decision making can become characterised by what are called ‘externalities’, meaning that significant, intra-system effects of particular, individual decisions are ignored in the decision making calculus that is at work. Related market effects that are not taken into account in procurement decisions are just an example of this much more general phenomenon, and their existence points to systemic weaknesses in the arrangements as a whole. In a nutshell, co-ordinating mechanisms are inadequate.
- 3.3.22. From a practical policy-making perspective it is advisable not to become excessively utopian in the face of this, identified challenge. Externalities will always be with us, and they abound in competitive market contexts too. A practical approach, therefore, is better based on a search for more egregious examples of the phenomenon (‘external effects’) which offer good prospects for the development of mitigating policies. The supply of enteral feeds to the NHS is a candidate example for adoption of this approach.
- 3.3.23. The economic policy tensions between decentralised decision making and co-ordination at the level of a wider system are matched by tensions on the legal side of things. For sound administrative law reasons (e.g. to impair the development of arbitrariness and discriminatory conduct in decision making), in evaluating tenders it is not permissible for decision makers to take account of factors that are not specified in invitations to tender. As the CMU Guidance puts it, in its second “golden rule” concerning the weighting criteria and specification of the evaluation matrix (Section 6):

All evaluation criteria, including sub-criteria must be clear. The awarding authority must use criteria linked to the subject matter of the contract.

- 3.3.24. Thus, if in pursuit of the advantages of ‘division of labour’ and decentralisation the subject matter of the contract is relatively narrow, decision makers cannot then widen out the criteria to include, for example, related market effects. On the other hand, given the fragmented accounting structure within the NHS, simply widening the subject matter of the contract at the outset is not a simple get-out-of-jail card that opens up the route to a ‘whole health economy approach’. Widening the subject matter of contracts in this way can be expected to increase risks of judicial review on the basis that some or other relevant information (from the now much-wider information set that needs to be evaluated) has been ignored

in making a particular decision²⁰. The bigger the information assessment task, the less likelihood there is of decentralised decision making units having the capacity to undertake it in a lawful way.

- 3.3.25. As discussed above, related market effects characterised by initial procurement decisions that then have significant influence on later, related procurement decisions tend to give rise to price structures in which profit margins on supplies are low or negative for the initial contract and then significantly higher for the ‘follow-on’ supplies. We noted above that this is not necessarily a problem in general, but it does create difficulties for the evaluation of contracts for the supply of enteral feeds. Specifically, it is a matter of observation that prices are very low (i.e. well below costs of supply) or zero for products and services supplied in secondary care contracts, but prices for supplies in the primary sector via the FP10 route are not.
- 3.3.26. If then suppliers are competing for contracts at close to zero prices, it follows that there will tend to be only very small differences in their price offers. Moreover, these prices will not reflect the underlying costs of providing the relevant, specified products and services, so that prices will not perform their familiar co-ordinating function of signalling costs to buyers (which serves to link the two sides of the market), and differences in tendered prices may bear little or no relationship to the differences in ‘whole health economy’ expenditures to which the competing offers would lead.
- 3.3.27. What we see at this point is all the various factors – weighting and scoring systems, related market effects and price structures – working together to lead to an outcome that, in the language of competition policy and law, is not ‘normal competition’ or ‘competition on the merits’. Very small differences in prices that are afforded excessive weight in evaluation criteria can have large consequences that are not at all closely correlated, even ordinally, with the price differences themselves.
- 3.3.28. Conceptual clarification of the distinction between competition in general (which simply means rivalry) and the notions of ‘normal competition’ or ‘competition on the merits’ becomes critically important at this point. We are not suggesting that the existing arrangements lead to weak competition in the sense of limited rivalry between enteral feeds suppliers. Rather, the point is that competition per se is not actually a public policy objective, in general as well as in health sector.
- 3.3.29. What public policy seeks are forms of competition that work well for end consumers. Its merits are assessed on this basis and in a well-governed economy meritorious competition will be ‘normal’. On this basis, we are led to the

²⁰ Law and economics come together at this point. Wider contracts imply a lesser degree of division of labour, the ‘labour’ in this case being devoted to the collection, organisation, interpretation and use of information. Less specialisation tends, on the economics, lead to lower effectiveness/productivity. Lower effectiveness in processing information increases the risks of judicial review.

conclusion that competition for the supply of enteral feeds under current procurement arrangements cannot reasonably be described as 'normal competition'.

4. Summary and ways forward

4.1. Summary

- 4.1.1. The problems identified in the preceding discussion will likely be familiar to those engaged with issues surrounding the supply of enteral feeds to the NHS, even if some of the economic perspectives presented are not. They can, therefore, be quickly summarised as follows.
- 4.1.2. The procurement arrangements give rise to an asymmetry in the way that contractors and suppliers assess the value of contracts to them. In general, suppliers' perspectives are the more aligned with value to the NHS as a whole, whereas procurement authorities are focused on narrower budget implications of a particular part of the NHS and their decision calculus fails to take account of the likely effects of their decisions on other budgets.
- 4.1.3. This gives rise to a significant failure/distortion in pricing mechanisms: prices do not reflect underlying economic factors that should be relevant to decisions in a well-functioning set of arrangements. The result is a form of competition that would, in a competition law and economics context, be classified as 'not normal'. Put another way, there is a failure to establish 'competition on the merits'.
- 4.1.4. There is clearly something wrong with arrangements that cause considerable time, effort and other resource costs to be devoted to the procurement of products and services that, in the event, turn out to involve relatively modest levels of NHS expenditure. When contractual, financial expenditures are low, the financial benefits of fine-tuning arrangements in a search for yet further reductions in those expenditures will likely be substantially lower still. Viewed narrowly, the costs of the arrangements appear to greatly exceed the likely financial benefits.
- 4.1.5. The root causes of this outcome appear to lie in 'co-ordination' failures. Decisions are decentralised to local procurement authorities but the evaluation criteria are not structured in ways that reflect the implications of those decisions for the NHS and its patients as a whole. This is the problem underlying the CMU's appeal, in its Guidance, for a 'whole health economy' approach. In technical terms, the rules under which CCGs operate give rise to substantial 'externalities', and contract prices for enteral feeds bear no relationship to economic costs. Those prices reflect neither the narrow economic costs that suppliers incur in providing feeds, equipment and services, nor the wider economic costs to the NHS that might be said to be 'caused' by the relevant procurement decisions.
- 4.1.6. The problems are magnified by specific features of the procurement arrangements that have developed in practice. Prominent among these are (a) the favouring of near-exclusive contracts, which are liable to have chilling effects on competition over longer periods of time and (b) the scoring systems under in tender

evaluations, particularly in relation to the scoring of competing offers where significant weight tends to be given to almost trivially small differences in price.

4.2. Ways forward

4.2.1. Given the nature of the issues raised, we end with a series of ‘suggestions’. Some of these are relatively specific and in these cases they can be read as ‘recommendations’. However, the more fundamental problems raise issues that can reasonably be described as matters of ‘market governance’ or ‘rule-making’. In relation to these, some rather fundamental thinking about how procurement arrangements are organised is warranted, and the relevant suggestions take the form of indicating the kinds of options that might be considered in future policy deliberations.

S1 Recognise the nature of the underlying issue, which is a lack of effective co-ordinating mechanisms in a set of arrangements that currently seeks to decentralize price determination for secondary sector supplies. In technical economic terms, the current arrangements give rise to dysfunctional ‘externalities’.

S2 Recognise that one option for resolving the issues is via national pricing throughout the whole NHS. National pricing is currently the dominant approach in primary care, notwithstanding the emergence of PCRS type arrangements. Given the nature of the relevant products and services, there appears to be no obvious reason why normal price competition could not be effective on a national basis: the products and services do not, for example, give rise to the same types of market power issues as patented pharmaceutical products.

S3 National pricing options would likely require some reconfiguration in the role of the ACBS. Specifically, the ACBS’s role would expand in significance. Obvious options for consideration here include re-constituting the ACBS as a statutory authority, establishment of more formal processes for evaluation, and providing it with increased resources. In relation to the last of these, we note that the additional resourcing required could be expected to be very considerably lower than the resources saved at the CCG level.

S4 Options based on retention of the decentralised price determination of current arrangements, particularly in the secondary sector, require that a great deal more attention be paid to market governance, i.e. to the ‘rules’ required to eliminate or mitigate the kinds of ‘externality’ problem identified. Effective decentralisation requires a strong ‘centre’, but one focused on a different type of task than that undertaken in a ‘unitary organisation’, the task of determining rules not outcomes. This is a legislative rather than an executive function.

- S5 Again this points to a movement toward enhancing the role and powers of central co-ordination bodies. Developments might include transforming CMU Guidance into binding rules, with the corollary that formality and resource levels be increased. Given the complexities involved, there could also be stronger enforcement arrangements to ensure that the rules established for tender processes are observed in practice, e.g. to ensure that re-tenders occur at the designated time.
- S6 It would be advisable for Guidance to explicitly require that those responsible for procurement take account of possible effects on future competition when tendering for enteral feeds, in order to counter biases arising from short-termist or ‘myopic’ approaches to matters. Among other things, this would help procurement authorities become aware of the pitfalls of creating ‘incumbency advantages’ that may have foreclosing effects on suppliers who might otherwise compete in future tender rounds (and that, in the limit, may cause some of those suppliers to cease trading). Such effects can be mitigated by well-constructed procurement processes, for example by shifting to a more reliance on multi-sourcing and to a lesser degree of approximation to exclusivity.
- S7 As is the case now in relation to Guidance, strengthened procurement rules should govern matters such as contract durations, re-tendering requirements, scope of contract, unbundling into lots, weighting and scoring of bid evaluations, but they should also be much more geared toward harmonisation across the range of procurement authorities based on ‘whole health economy’ objectives.
- S8 To give rather more specificity to the kind of rule-making we have in mind, an enhanced CMU or successor body might contemplate imposing a general requirement that, in awarding points scores for prices bid by suppliers, bids be evaluated relative to a national benchmark price (NBP), determined by the CMU or ACBS from time to time, on the following basis:

$$\frac{NBP - \textit{Price offered by bidder}}{NBP} \times \textit{Maximum Points}$$

- S9 In the shorter-term, recognising that more fundamental developments take time, there is scope for bodies such the CMU and ACBS to start to develop their thinking and procedures in the desired direction, for example by offering more explicit Guidance and developing their own procedures. The underlying aim should be to guide the incentives surrounding procurement decisions towards a structure that is more reflective of the overall benefits that competing offers to the NHS as a whole, and less based on financial benefits to the budget of one commissioning body, particularly when the latter, narrower benefits are achieved either by shifting costs on to the budget

of another part of the NHS or are only achieved in the short-term at the expense of less competition for NHS contracts in the longer-term.

S10 Although on the evidence that we have seen we believe that the incremental costs of strengthening some of the central NHS institutions in the ways suggested would be dominated by the cost reductions that are potentially available – including in the tendering costs imposed on suppliers, at least some of which will ultimately be borne by the NHS itself – it would, as always, be prudent to assess this trade-off ahead of any significant changes. The development of procurement contracts for central feeds originated in a rather *ad hoc* way and it is far from clear that there is any sense of just what costs the current arrangements impose on the NHS, either in terms of the resource costs of running the tenders themselves or in terms of the indirect costs to which the procurement arrangements give rise as a consequence of inappropriate evaluation methodologies or of unintended effects on competition.