



Homecare Medicines

Towards a Vision for the Future

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Foreword



The importance of homecare medicines for patients cannot be underestimated. There are up to 200,000 people in England who receive this service, which has helped to transform their lives whilst they suffer from chronic or stable conditions that require regular

treatment and monitoring. Since 1995, the NHS has been able to provide these homecare services at patients' homes and in the last four years there has been a rapid development of services which now incur around £1 billion expenditure each year.

The Chief Pharmaceutical Officer at the Department of Health asked me to undertake a review of the homecare medicines supply and associated services in England to establish what are the current challenges and issues and what should occur in the future. The review was commenced in November 2010 and has sought to address this.

The review has found that there are indeed many examples across homecare providers, NHS providers and commissioners of admirable services and best practice, which help patients secure high quality and effective services to them. However, these were not the norm; they were the minority because there are fundamental issues which need to be addressed to ensure we can maintain high quality suppliers who can flourish in the market; providers who have effective leadership; governance arrangements and monitoring arrangements that are in place; commissioners who need to work in a more collaborative manner across health systems to secure the best value for money arrangements

for homecare and for patients we need a sea-change in their involvement in the design, commissioning and operation of such services. The key recommendations of the review are:

- In a rapidly expanding market place, there is a need to provide better services to patients and the taxpayer by securing more open, collaborative procurement of homecare medicines delivery and services, which are based on modern commercial arrangements, underpinned by improved clinical governance arrangements between NHS Trusts and homecare suppliers and a set of clear industry standards. In this way there can be the development of safer, effective and efficient homecare medicine which works in the best interest of the patient and taxpayer.
- The internal governance frameworks of NHS Trusts should be strengthened given the rapid growth of homecare medicine. The Trust Chief Pharmacist should become the 'Responsible Officer' for all homecare medicine services and be accountable for these services to the Trust Chief Executive Officer. The involvement of the Trust's Medical and Nurse Directors needs to improve around the design, operation and control of homecare medicine. Homecare medicine needs to be set in the context of a strategy for chronic and stable conditions for patients who are best managed at home and should be part of integrated planning between Trusts and their commissioning agencies. As such a strategy for homecare medicine should be developed with the local drugs and therapeutics committee and an annual plan which the Trust Chief Pharmacist needs to deliver.

Through collaborative procurement mechanisms

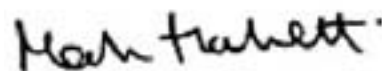
** Throughout this document we generally use the term homecare medicines. This incorporates prescribing, dispensing, delivery and associated services*

between NHS Trusts and commissioners, better value can be delivered for patients and taxpayers to enable high quality, responsive and more cost effective services to the patient and taxpayer.

- Commissioning agencies have a vital role to play in the strategic development of homecare medicine and the management of authorised providers to deliver effective homecare medicine to patients. This will require them to work with acute providers, as authorised provider, to deliver an effective strategy and annual plan to involve homecare in collaborative procurement and develop incentives between the authorised provider and themselves to maximise value for money.
- Moving forward, patients and patient representatives should have a much greater role in the design, operation and monitoring of homecare medicines delivery and services, with the authorised provider organisations delivering them. Patients are at the heart of homecare medicine and should be listened to and offered choice on styles of delivery and services and be involved, to assist with monitoring of the quality of the service.

In looking at these issues, I have personally been focused around the need to influence change which results in better services for patients. The recommendations the review has presented are based on a coherent set of principles and approaches which, when taken together, ensure just that.

I would like to thank the numerous people who have helped me with this review (**Chapter 7** provides full list of working members) from those within the Civil Service, the NHS, the Homecare industry and professional associations and the patient representative groups. I will especially mention Howard Stokoe, Liz Payne, Chris Theaker, Phil Deady, Andrew Alldred, Allan Karr, Alison Clough (ABPI), Warwick Smith (BGMA) and Nick Payne (NCHA). Through us all working in an open and participative manner we have been able to develop, I hope, a guiding coalition of leadership together that now can take these recommendations forward.



Mark Hackett

Chief Executive, University Hospital Southampton
NHS Foundation Trust

Conclusions and recommendations

Market problems

- A rapidly expanding market with high concentrations of business in certain sectors, with new entrants and certain sectors demonstrating low/high market concentrations.
- Cash flow for certain homecare providers is unstable, given arrangements between homecare providers, manufacturers and the NHS around payments.
- A perception of unreasonable risk transfer to the homecare providers from commissioners or acute providers.
- ‘Clunky’ arrangements to administer homecare medicines delivery and services which are costly, labour intensive and not efficient or effective in some cases.
- Weak contractual, governance and operational control mechanisms to set, operate and monitor contractual arrangements.
- Current procurement mechanisms are not co-ordinated or of sufficient scale for patient populations to secure best value for money.
- These procurement mechanisms are opaque when it comes to homecare provision in respect of cost and profit levels, due to the way VAT is applied and other factors considered.
- Managers and clinicians do not generally understand the direct supply of homecare medicines from manufacturers. This supply involves the bundling of products and services, and clinicians are not engaged as customers.
- There is currently no standardised contract document which covers all homecare medicines delivery and services. This is needed to identify basic relationships across the NHS, providers and commissioners, as provided in the National Homecare Medicines Committees recommended documentation.
- The ‘manufacturers only’ supply routes for homecare medicine results in barriers to entry for other suppliers and the NHS, and causes duplication as well as not integrating with whole health system working.
- VAT is a potential barrier to entry for NHS organisations wishing to move into the homecare medicines market.
- There are problems with current patient equity and access to homecare medicines.

Governance in NHS trusts and across the market

- Chief Pharmacists are not always involved in homecare medicine and without this engagement acute trusts cannot maintain and improve control in this key medicines management area.
- Internal acute sector governance processes, in many cases, lack rigour, transparency, clinical control and engagement. Major improvements are needed to ensure that these are met, together with cost effectiveness of homecare medicine delivery and monitoring.
- High transaction costs in operating homecare medicine, given the weak use of IT and involving processes between hospital pharmacy, finance departments and PCT.
- The accreditation system does not set the visible minimum standards for homecare medicine suppliers that the NHS should expect

competent suppliers to have in place, so as to ensure they act in patients' best interests.

- The lack of mechanisms to track homecare medicine could impact on the NHS seeing full value for money from the Department of Health's Pharmaceutical Price Regulation Scheme.
- The role of medical and nursing directors and trust chief pharmacists needs to be strengthened in hospitals and across commissioners, to operate better homecare medicine.
- The current mechanisms for ordering homecare medicine needs greater control, i.e. via designated pharmacists and pharmacies, but the role of the chief pharmacist in trusts needs change to move to services, not just product supply, with greater involvement of trust medical and nursing directors.
- The current arrangements for homecare providers to work to the acute hospital customer are weak, and governance systems are not aligned and integrated into a single system.
- Errors and risks are not assessed and reported in the homecare medicine setting, consistent with the application of National Patient Safety Agency (NPSA) guidelines in the acute sector.

Collaboration across organisations

- There is no clear national or regional formula which enables hospitals and commissioners

to undertake procurements which are collaborative, and encourage maximising value for patients and the taxpayer.

- There is no incentivisation to reduce patients on homecare medicines delivery by using community pharmacy alternatives, or change service models that are not aligned to deliver the best interests for patients, where this might be appropriate.
- There are insufficient opportunities for NHS providers and homecare providers to work on collaborative models, to ensure effective local systems for managing patients with stable conditions and chronic disease.

Patient involvement

- There are limited examples in England where patients play a part in monitoring homecare providers alongside trust pharmacists, trust medical directors and directors of nursing, to secure and improve homecare medicines service performance.
- Patient centred solutions could be improved around delivery, storage, conformance to medicines and quality monitoring of the service.
- Levels of wastage of homecare administered therapies could be reduced through the involvement of patients.

The recommendations to address and deal with these conclusions

In a rapidly expanding market place, there is a need to provide better services to patients and the taxpayer by securing more open, collaborative procurement of homecare medicine, based on modern commercial arrangements, underpinned by improved clinical governance arrangements between NHS trusts and homecare suppliers and a set of clear industry standards. In this way, there can be the development of safer, effective and efficient homecare medicine which will work in the best interests of the patient and taxpayer.

- There are a number of new entrants into the homecare market with synergistic approaches with the NHS, who should be encouraged to develop.
- There is a need to provide stability to new and existing homecare providers in the market by identifying stable profitability levels, cash flows and realistic cost bases. This should be achieved through more collaborative purchasing (and specification design) with the NHS, to ensure both NHS organisations and suppliers understand the level of profit and return for the homecare provider, in a transparent manner and by working together to reduce costs of homecare medicines delivery and services.
- The NHS needs to develop stable contractual frameworks for the homecare medicine organisations, which are of sufficient contract duration to enable services to secure the best value for the patient and the taxpayer. Through the development of more open, collaborative procurement involving commissioners, NHS providers and patients, the NHS can set more effective service specifications. These should centre on the need to meet patient choice, diversity and quality issues, and benefit the taxpayer through commitment to planned volumes, incentives to reduce demand for homecare where clinically and cost effectively appropriate. This would enable long-term investment from homecare suppliers in developing effective e-homecare services, which reduce current transaction costs to the NHS, and the homecare supplier, in operating and monitoring service contracts.
- Homecare suppliers should be prepared to take appropriate, proportionate risks in return for long-term service contracts, which enable investment in new technology, new service levels and cost efficiency. These should be part of the basis on which new service contracts are awarded and these value chain benefits, open and transparent to NHS customers.
- The NHS should pursue an immediate unbundling of homecare medicine dispensing, delivery and associated service costs. The pharmaceutical suppliers and the NHS should define these costs and reduce them from their current prices, (which legitimately include distribution costs embedded in the manufacturers' NHS pricing structures).
- Homecare providers should have completely integrated clinical governance with the NHS provider who is their customer, which enables assurance for the NHS on:
 - o Compliance with current regulatory conditions and frameworks.
 - o Setting of service standards for homecare medicines delivery and services.
 - o The training and development of staff to secure these standards.
 - o The operational management of staff to

Note: distribution covers the supply of product from manufacturer to the point at which it is dispensed. Delivery is associated with the supply of the product from the point at which it is dispensed to the patient.

- o ensure the service specification is delivered.
 - o The reporting of adverse incidents, service failures, patient satisfaction, medicines compliance and other relevant issues should be produced by the homecare provider, at least monthly and in a way which integrates with NHS providers, clinical governance reporting systems and national reporting, e.g. NPSA incident reporting.
 - o The effectiveness of the service to the patient.
- The homecare providers and NHS should have a clear set of industry made standards which cover:
 - o The selection, registration and discharge of patients.
 - o Service Quality Goals.
 - o Reporting against governance standards including linking into NHS reporting system effectively.
 - o e-Transactions, e-homecare and management information requirements/ service levels.
 - o Patient management, wellbeing safety, experience, outcome, confidentiality, management and monitoring.
 - o Communications.
 - o Compliance with medication and any incidents which relate to this.
 - o Performance monitoring and management.
 - o e-Transaction mechanisms which set out a common platform for interaction between the patient, homecare provider, the NHS provider and the commissioner, to enable effective ordering, delivery and management of homecare medicine at the lowest transaction cost. This will enable low switching costs between providers, and each party would be expected to invest in the necessary and sufficient information system to secure this, from the contract set between them.
- o Incentives for improving value for money for homecare by reducing levels of wastage, distribution costs, costs of service delivery or supply of homecare medicine, as well as moving patients to other forms of medicines supply, e.g. community pharmacy and reducing costs to the NHS.
- o Developing clear systems for reporting and managing risks in the delivery of homecare medicine between the homecare provider and the NHS.
- o A robust governance framework which describes the implication of breaching such industry standards and the relevant involvement of pharmaceutical, NHS and homecare providers to ensure patients and the taxpayer are protected. This should be developed with the National Homecare Medicines Committee, Association of the British Pharmaceutical Industry, National Clinical Homecare Association, British Generic Manufacturing Association and the NHS utilising the forum of the NHMC.
- These industry standards should be set in an accreditation framework which will accredit homecare companies to enter into NHS contracts. This 'kite marking' or similar accreditation process would also include financial, logistical and operational governance requirements. The CMU working with the NHS should do this, working with relevant industry representatives utilising the forum of the NHMC.
- The homecare providers need to work with NHS providers to ensure cost effective, patient centred services are delivered, and these ensure maximum compliance by patients to therapies, whilst providing the relevant information on outcomes at a clinical and patient level, reflecting the efficacy of the medication.

Acute providers

NHS Trusts should consider strengthening their internal governance frameworks given the rapid growth of homecare medicine. The Trust Chief Pharmacist should become the 'Responsible Officer' for all homecare medicine and be accountable for them to the Trust Chief Executive Officer. The involvement of the Trust's Medical and Nurse Directors needs to improve around the design, operation and control of homecare medicine. Homecare medicine needs to be set in the context of a strategy for chronic and stable conditions for patients who are best managed at home and should be part of integrated planning between Trusts and their commissioning agencies. As such a strategy for homecare medicine should be developed with the local drugs and therapeutics committee and an annual plan which the Trust Chief Pharmacist then has to deliver.

Through collaborative procurement mechanisms between NHS trusts and commissioners better value can be delivered for patients and taxpayers who will enable high quality, responsive and more cost effective services to the patient and taxpayer.

- The Trust Chief Pharmacist should be accountable for ensuring the safe and effective administration and supply of medicines in homecare.

To discharge this duty all trust chief pharmacists in England should:

- o Set the strategy for homecare medicines delivery and services, and their supply with the medical and nurse directors in their trusts, to ensure the patient and taxpayer are protected, and get the most cost effective and safe services available, which meet their needs.

- o Work with Clinical Directors to ensure that appropriate patient cohorts are identified for homecare treatment, and realistic demand projections are set.
- o Ensure the development of a shared governance framework which states clearly which aspects of care are the responsibility of the hospital, homecare supplier, general practitioner, patient and other healthcare professionals.
- o A homecare medicine specification and charter should be set for patients receiving homecare which will explain:
 - The treatment plan.
 - How initial and repeat prescriptions will be produced and by whom.
 - The duties of the homecare company
 - Who is responsible for routinely monitoring clinical and laboratory results.
 - The arrangements for reporting patient safety incidents, performance activity and outcome monitoring.
- o Ensure that the pharmacy is the only place where homecare medicine prescriptions are issued, and that all other areas cease, to ensure effective operational control of procurement, ordering and invoicing into the appropriate local pharmacy system, and its link with CMU's Pharmex system nationally.
- o Implement appropriate changes to the current NHS Trust pharmacy systems — particularly JAC and Ascribe — which enable direct inter-charge with the trust's finance system, and enable direct communication with the homecare supplier for ordering, invoicing and patient tracking.

- o Ensure effective resource is available to manage the homecare medicine contract to fully deliver its contract requirements.
- o To be responsible, with the Trust Medical and Nurse Directors, homecare provider and patient representatives, for reviewing the service from the homecare provider at agreed regular intervals.
- o The Trust Chief Pharmacist should be the responsible officer for all homecare medicine contracts.
- o Providers should have a clear set of tests based on:
 - Patient choice — relevance, convenience, safety.
 - Choices — productivity, relevance and effectiveness.
 - Finance — value for money.

To determine a number of key tests to agree what products and services are suitable for homecare provision. This programme should be agreed with the Medical and Nurse Director, who are accountable for service quality in the Trust, and the Trust Director of Finance regarding financial implications.

An annual programme for homecare medicine should be set by the Trust Chief Pharmacist. This would describe the new and existing homecare medicine, and would be reviewed with the plans concerning method of delivery, scope of service responsibility and levels of quality and financial impacts. This should also be agreed with local commissioners, as an annual plan.

- o The Chief Pharmacist should be accountable to the Trust CEO for the delivery of the annual plan. The relevant Clinical Director

will be responsible for the individual therapy plan and its execution, and the Medical and Nurse Directors accountable for delivery of effective quality assurance mechanisms, and the monitoring of delivery of the service in accordance with the agreed governance and operational arrangements.

- o Trusts should consider the inclusion of renal, parenteral nutrition feeds and other therapies to become part of the Trust Chief Pharmacist's remit to maximise benefits to patients and the healthcare system if these are delivered by homecare routes.
- o NHS providers should enter into collaborative procurement mechanisms at a national or regional basis, for the delivery of homecare medicine. There should be a standard national NHS framework agreement for homecare medicine which covers in its scope:
 - Source required
 - Clinical governance arrangements
 - Financial management arrangements
 - Patient engagement/monitoring
 - Quality assurance mechanisms
 - Remuneration arrangements
 - Incentives
 - Other common contract conditions
- o This will be supplemented by a series of contract appendices, which may vary or enhance national conditions based on local collaboratives agreed with commissioners and NHS providers. These schemes will also involve a common service specification which will set out what the authorised organisation, i.e. NHS Trust, requires of the homecare solution contracted for and clear output standards for patients, payer and NHS trusts and the homecare provider.

- o There should be a clear set of national and regional services purchased to maximise value to the NHS, whilst remaining responsive to patients locally to provide national value for money and supplier certainty in a £1 billion market.
 - o The commissioner and NHS trust should agree for national and regional contracts a defined savings share from the switch to homecare medicine or contract renewal for homecare. Typically a formula might be based on a minimum 50:50 share. For the NHS provider it will provide for an incentive as well as the costs of meeting the administration of the homecare contract in its entirety.
 - o There must be clear incentives offered to the homecare provider to continually improve value for money across the lifetime of the contract. There should be clear financial incentives to the supplier for improving savings to the NHS.
 - o Collaborative commissioning should secure from the homecare supplier, complete openness on profits and costs of delivering homecare supply.
 - o Homecare suppliers should work with NHS providers to second staff from NHS providers to the homecare service, to deliver improved team and system working.
 - o The clinical responsibility of the GP, consultant, specialist nurse, homecare provider and pharmacist should be specified in the service specification.
 - o The Trust drugs and therapeutics committee should approve the annual homecare medicine plan.
- Good practice suggests that the Trust Chief Pharmacist, Medical and Nurse Directors and patient representatives review the performance of the homecare contract at least six monthly, with the homecare supplier to identify areas of strength and areas for improvement.

Commissioning

Commissioning agencies have a vital role to play in the strategic development of homecare medicine and the management of authorised providers to deliver effective homecare medicine services to patients. They can enhance their role here by working with acute providers to deliver an effective strategy and annual plan for homecare, involvement in collaborative procurement and develop incentives between the authorised provider and themselves to maximise value for money.

- National and regional procurement for homecare medicine should be based on the best advantage for patients and the taxpayer. These should be specified and mandatory, similar to national and regional specialised services commissioning arrangements. These contracts should be held by an authorised provider organisation on behalf of the commissioners and providers.
- In considering homecare medicine, the following strategic recommendations are made:
 - o Commissioners should consider how homecare fits with their chronic disease or stable disease models and other strategic implementation.
 - o The ‘whole life cycle’ cost of introducing a homecare service should be considered, not only the savings from VAT but the impact on direct hospital incomes and restructuring, which could have substantial savings to the health economy.
 - o Develop a three-year strategy for non-tariff and tariff therapies.
 - o Commissioners should ensure that as part of national or regional procurement there are clear up front agreements on the share of financial savings with providers.
 - o To assess the market for collaboration or competitive approaches to secure change in service delivery models.
- Commissioners need to participate in the procurement of homecare provision with the authorised organisation. They will require the authorised provider organisation to manage the contract with the homecare provider.
- Commissioners should ensure their payment systems are integrated with the pharmacy system in the authorised organisation, to ensure rapid and prompt payment within 28 days of a valid invoice being approved by the authorised provider organisation.

Patients

Patients are at the heart of homecare services and should be listened to, offered choice on styles of homecare delivery and be involved, to assist with monitoring of the quality of the service. Moving forward patients, and patients' representatives, can play a much greater role in the design, operation and monitoring of homecare services with the authorised provider organisation for homecare services.

- **Develop a clear patient specific customer charter to enable patients to understand their homecare services and how they can change them.**
- **Patients should be offered by the NHS a much greater choice of homecare or hospital services.**
- **Patient representatives should be involved with NHS providers and commissioners input into the formulation of service specifications for homecare services.**
- **There is a need to ensure patients have a greater involvement in the operation of homecare services where they have the physical and mental capacity to do so. In**

designing homecare services, there should be:

- o Acute Trusts should consider introducing suitable electronic mechanisms for patients to communicate directly with NHS authorised organisations and homecare suppliers, to confirm that they have satisfactorily received their products or service, that they are satisfied with the service, and that they, or a carer or professional, administered the therapy at the correct level. They could also report comments, suggestions and complaints on the service.
- o They should be offered a choice of delivery times, within reason, which meet their needs.
- o Patients' views should be sought on the operation of the service, and these should form part of the governance systems.
- o Homecare providers will be subject to penalties should levels of patient satisfaction with the service fall below agreed and measured levels, after a period of time, to improve the service.

Commercial Medicines Unit (CMU)

The Commercial Medicines Unit (CMU) role in homecare medicine should be strengthened to ensure the delivery of an effective market which is operating to clear standards and providing high quality services to patients. In consultation with the NHS, professional bodies and patients it should decide which homecare services are best procured nationally or regionally and monitor trends in homecare provision and delivery.

The CMU should:

- Develop suitable national and regional contract documents for homecare.
- Identify the homecare services which should be nationally and regional procured with target levels of benefit realisation (financial and non - financial).
- Monitor the compliance with entry of hospitals into Pharmex via hospital pharmacy systems and take actions.
- Develop, manage and enhance the industry wide standards for homecare with suitable inputs from NHS, industry and other sectors.
- Provide strategic advice to support the commissioning of homecare.
- Transfer the procurement for renal and HPN to homecare medicines delivery service procurement framework, at a regional or national level.

Department of Health (DH)

The Department of Health (DH) should create the right climate for homecare medicines to develop in a co-ordinated manner over the next decade, to continue to ensure high quality services to patients. The Department of Health should create a forum reporting to the Chief Pharmaceutical Officer, which monitors the development of homecare and its operation. These responsibilities should transfer (subject to legislation) to the NHS Commissioning Board from April 2013*.

- The DH should consider the sustainability of homecare medicines market given its dependence on legitimate VAT benefit. DH should reach a conclusion on whether this represents an effective mechanism to fund services in the long-term, and its effect on NHS providers who are effectively barred from entry into this market.
- Work with the NHS to develop a feasibility of a homecare tariff for services defined on homecare.
- Create a forum to oversee the development of homecare, its operation and the best methods to secure ongoing benefits for patients and taxpayers.
- Recognise and understand software interfaces to deliver the e-commerce system with homecare providers to reduce transaction costs in discussion with the NHS.

**In the body of the report and appendices the contributions were made prior to any formal structural changes.*



Introduction

1

Homecare medicine delivery and services

- 1.1 Every year NHS trusts and Community Health Services in England spend about £3.9 billion on prescribed medicines. Homecare medicine contributes an estimated £800 million towards this figure. This is a review of the management and characteristics of homecare medicine.

Remit of the review

- 1.2 The DH Chief Pharmaceutical Officer, Dr Keith Ridge, invited Mark Hackett, Chief Executive of University Hospital Southampton NHS Foundation Trust, to undertake this review of homecare medicine and provide advice.

Homecare medicine supply — definition

- 1.3 A homecare medicine delivery and services can be described as being one that delivers ongoing medicine supplies and, where necessary, associated care, initiated by the hospital prescriber, direct to the patient's home with their consent. The purpose of the homecare medicines is to improve patient care and choice of their clinical treatment.¹
- 1.4 The Chief Pharmaceutical Officer was prompted to initiate the review because he:
- associated the rapid expansion of homecare medicine with a lack of national visibility and was concerned that, without this understanding, the DH was unable to advise ministers on policy options.
 - related the DH's inability to secure a national understanding of homecare medicine with concerns about how the NHS managed this business, and the thought it was giving to strategic intent.
 - recognised that 'getting homecare medicine right' was important to taxpayers and patients, not least because of the contribution that homecare medicine supply will play in delivering a strategic shift of caring for patients in their own homes.

Objectives for the review

- 1.5 The following objectives for the review are taken from its terms of reference. **Appendix A** provides the full terms of reference.
- 1.6 Provide advice on what constitutes best practice with respect to the procurement of homecare medicine including:
- Financial governance
 - Clinical governance
 - Operational efficiency
- 1.7 Provide advice on what opportunities there are for collaboration across the NHS on homecare medicines procurement.

¹ *National Homecare Medicines Committee – 2011*

- 1.8 Develop guidance for the NHS on when homecare medicines would be an appropriate model of care and, specifically, where it is not.
- 1.9 Identify, with support from the wider clinical community, the opportunities to expand and develop the use of homecare medicines.
- 1.10 Provide advice on the actions required to improve the commercial performance of the homecare medicines market (to achieve better value for money, and ensure there is competition); this may include suggestions for policy change.
- 1.11 Provide advice on the precautions necessary to manage the risk of company failure as commercial performance is challenged.
- 1.12 Provide guidance on how the NHS can ensure appropriate collection, collation, dissemination and analysis of information on procurement of homecare medicines, (required for Pharmaceutical Price Registration Scheme, strategic and operational management).
- 1.13 Provide advice on what future work, beyond medicines, may be helpful in developing homecare services for the NHS.
- 1.14 Inform the Quality Innovation Prevention and Productivity (QIPP) agenda

Methodology

- 1.15 To undertake the review Mark Hackett has drawn on a combined panel of support — steering group and working group members detailed in **Appendix B**
- 1.16 To assist with the review the panel examined information that was already available, and engaged with a variety of stakeholders over a nine-month period. This approach ensured the review consulted with the right people, and listened to their views before making final recommendations.
- 1.17 The review panel met with and examined information from the following organisations and areas:
 - Working group
 - Stakeholder wide workshop
 - Beacon sites
 - NHMC
 - Pharmex data, e-PACT and BTT
 - NHS Trusts — clinical specialists, in rheumatology, oncology, cystic fibrosis, respiratory, anaemia and renal
 - Chief Pharmacists
 - Directors of Finance
 - National Patient Safety Agency

- Industry associations — ABPI, BGMA, NCHA
- Individual industry organisations
- Patient groups/representative groups
- Alliance Boots

The changing NHS – limitations of the Review

1.18 The homecare medicine market is complex and the Government's plans for the future of the NHS have not been finalised before this review has been completed. In addition, the review panel did not consult with the NHS on a formal basis. As a result there are inherent limitations. For example, the review does not capture aspects that relate to the emerging relationships between social care and healthcare.



Benefits of Homecare Medicines

2

- 2.1 There are many benefits in using homecare medicines delivery and services. For example, bulky and heavy medicinal products such as renal dialysis solutions, enteral and HPN feeds can be delivered direct to patients homes. Homecare medicines delivery and services can also release hospital beds and return patients to their homes earlier. Patients do not need to make visits to hospital to receive periodic medicine treatment or prescriptions, and is consistent with the theme of 'increased patient choice'.
- 2.2 Outpatient and day case visits made by patients to receive periodic medicine treatment can be reduced, thus freeing those appointment slots and increasing efficiency.
- 2.3 Hospitals can therefore reduce their need to closely manage patient care. This may also benefit commissioners in terms of PbR tariff patient attendance fee. Contracting for specialist homecare services ensures that these patients are not a burden on community services within primary care organisations.
- 2.4 The introduction of innovative new medicines, associated with formulations and presentations that make them easier and safer to administer, are increasing their viability for homecare supply.
- 2.5 As a result homecare medicine can be seen as increasingly offering opportunities to redesign patient care pathways, with the medicine playing the part of key enabler for change.
- 2.6 Recognising these opportunities and the associated role of homecare medicine will be critical if patients are to be able to choose and benefit from end of life care in their own homes, and in particular the way the Government decides to take forward recommendations put to it following the independent review it commissioned.²

² *Palliative Care Funding Review — Funding the right care and support for everyone 2011*

Summary of benefits: patient and homecare provider perspectives

The NCHA identified the following benefits associated with homecare medicines:

Improved treatment outcomes

- Additional treatment capacity of clinical homecare may mean faster access to treatment.
- Improved adherence to treatment through regular contact with, and education of patients.
- Fewer and shorter hospital visits means less risk of hospital-acquired infections.

Access to hospital professionals at all times

- Access to advice from dedicated teams of healthcare professionals, sometimes 24 hours a day.

Time and economic savings

- Less travel, hospital parking, childcare, time off work, reduction in clinic times.

Independence

- Greater control over treatment, ability to operate a 'normal' lifestyle.

Confidentiality

- Discreet and private.

Patient statement

“For people with Cystic Fibrosis, like me, and their families, the most positive aspect of having treatment at home via a ‘homecare system’ is being able to carry on with life as normal and maintaining independence. It enables adults with CF and parents of children with CF to continue to work and socialise, children can go to school and college, minimising disruption to their education. Additionally due to the need for people with CF to be segregated it can be extremely isolating to be an inpatient, particularly when your specialist centre is far from home. This means family and friends are less able to visit due to financial and time constraints. There are further financial implications with parents and partners only being able to get limited time off work and the need to arrange childcare for any siblings.

“From my own experiences I know a course of home intravenous (IV) antibiotics can be particularly tiring for those with CF, particularly at times of severe illness and the need to administer a first dose (often 1 of 3) at 6 am which means having to get up and prepare the dose at 5 am. Pre-mixed drugs that are delivered along with a fridge and any consumables required, means less time is required for the patient and the families to prepare and administer the drugs. Having everything pre-mixed and delivered to your home also decreases hygiene and safety concerns, meaning less stress for the patient and their family.

“Coupled with support from the Specialist CF team, who can provide monitoring of lung function, care of venous access devices during a course of treatment and collection of blood to monitor drug toxicity levels in the home environment, the administration of home IVs mean less disruption and allows people with CF the freedom from the hospital environment, away from the risks of cross infection, leaving them able to work and live their lives as normally as possible. This also results in people with CF being able to work more consistently and therefore contribute to UK GDP (gross domestic product) via the product of their work, national insurance and tax contributions.”

**Emma Lake – Senior Expert Patient Adviser
Cystic Fibrosis Trust**



Background

3

- 3.1 The Government puts patients at the heart of the NHS and everything that it does and is seeking to empower and liberate clinicians to innovate with freedom to improve health services.³
- 3.2 It also recognises that medicines can transform peoples' lives and add enormously to life expectancy.⁴
- 3.3 Homecare medicine brings the redesign of NHS services and recognition of the role that medicines play, together, around a single natural focus.

The medicines management landscape

- 3.4 The use of medicines plays a vital role in the delivery of high quality care and accounts for over 12% of NHS expenditure. In 2009 -10, the NHS drugs bill was approximately £11.9 billion, equivalent to around 12% of the entire NHS budget and was the biggest single item of spend after staff. Of this around £7.9 billion was spent in primary care and £4 billion in secondary care.
- 3.5 Approximately 75% of the total spend was on branded medicines and 25% on generic medicines (including appliances, testing agents etc.). This cost is increasing at a rate of about 4.6% per year and when associated costs such as monitoring and service costs are added, the true cost of medicines is much greater. Unintended costs may also arise through adverse drug reactions, which are estimated to account directly for 5% of all hospital admissions.⁵
- 3.6 Whilst the overall picture is one of increasing direct expenditure on medicines, this is not uniformly true across the whole health system. In primary care, total costs decreased by 0.7% from 2007 to 2008. Within hospitals prescribing costs increased by 15.2% from 2007 to 2008 for medicines prescribed and dispensed within hospital. For medicines prescribed in hospital but dispensed within community settings via the hospital FP10 route, the increase over the same period was 5.2%.
- 3.7 It is likely that there will continue to be an upwards pressure on expenditure for the foreseeable future driven by factors such as improving access to innovative medicines and increasing levels of ill health associated with a population that is living longer.

The Pharmaceutical Price Regulation Scheme (PPRS)

- 3.8 The National Health Service (NHS) spends over £9 billion a year on branded prescription medicines in the UK. The PPRS is the mechanism which the Department of Health (on behalf of the UK health departments) uses to control the prices of branded prescription medicines supplied to the NHS by regulating the profits that companies can make on their NHS sales.

³ NHS White Paper – Department of Health - Equity and Excellence: Liberating the NHS – July 2010

⁴ A new value-based approach to the pricing of branded medicines – Department of Health – December 2010

⁵ Pirohamed M, J S, Meakin S et al. Adverse drug reactions as a cause of admission to hospital: prospective analysis of 18820 patients: *British Medical Journal* 2004; 329: 15-19

3.9 In summary, the PPRS:

- allows companies freedom of pricing for new medicines (new active substances) but requires companies to seek the department's agreement for price increases, which are only granted if the reasons for the application meet the criteria for increases set out in the agreement
- requires companies with NHS sales of more than £35 million a year to submit annual data on sales, costs, assets and profitability and to repay the excess where profits exceed the agreed threshold
- provides significant support for research and development (R&D) and initiatives to encourage and reward innovation.

Further information is available on the DH website at www.dh.gov.uk/pprs

Payment by Results

3.10 Under the system of Payment by Results (PbR), most services delivered by hospitals are subject to a national tariff. PbR uses a national tariff of fixed prices that reflect national average prices for hospital procedures.

3.11 There are a number of High Cost Drugs (HCDs) that are excluded from the PbR tariff. They are typically specialist, and their use is concentrated in a relatively small number of centres rather than evenly across all Trusts that carry out activity in the relevant HRGs. These drugs would therefore not be fairly reimbursed if they were funded through the tariff. Excluding certain drugs means that additional funding can be locally agreed over and above the national mandatory tariff.

The NHS environment

3.12 The NHS comprises primary (community) care, secondary (hospital care) and tertiary (specialised consultant care e.g. cancer.)

Primary care

3.13 GPs write a prescription for drugs. The patient takes the prescription to a pharmacy where the drug is dispensed either for a flat rate prescription fee or on the basis of exemption, at no charge to the patient. Pharmacies are responsible for purchasing drugs either directly from manufacturers or through wholesalers. They are reimbursed by the NHS for the cost of these drugs.

3.14 Primary Care Trusts contract for services from GPs under the terms of the General Medical Services (GMS) contract. Cost effective prescribing is incentivised through GMS and local incentive schemes. Additional influence comes from guidance from national bodies (NICE), local formularies, PCT prescribing advice activity and other factors such as peer pressure, pharma marketing activity and patient pressure. Dispensing doctors may procure and dispense medicines.

Secondary and tertiary care

- 3.15 Hospital clinicians prescribe and drugs are dispensed by the hospital pharmacy. Hospitals are responsible for purchasing the drugs they dispense. They are not reimbursed directly but should draw on overall NHS revenue. (See section 3.10 on Payment by Results). Patients do not pay any charge for drugs supplied during a hospital stay, but charges apply on medicines associated with outpatient, A and E and day case episodes.

Homecare medicine supply

Origins and context

- 3.16 Against the background of the above explanations, the DH formally confirmed a third route of supply when it issued 'Purchasing high-tech healthcare at home' EL95/5. This stated that:

DHAs working with FHSAs, General Practitioners and hospital and community trusts should make provision through their contracts by 1 April 1995 to support patients at home whose treatments include the delivery of drugs together with other products and equipment needed to administer them, typically as packages of care

Appendix C provides EL95/5

- 3.17 Although this EL95/5 is now 'historic' it can still be considered a key reference in setting out the characteristics of homecare medicine supply with some aspects still being reflected through this report's recommendations.
- 3.18 Since the publication of EL95/5 the scope of homecare medicine has grown far beyond the originally identified therapies. It now includes both high and low technologies — products and services — and is now referred to as homecare medicines delivery and services.

High-tech Homecare Medicine and Services

- 3.19 The high-tech element of the service will include products and services such as:
- Injectable therapy, e.g. intravenous route
 - Oral therapies that require significant support such as blood level monitoring or special storage requirements.
- 3.20 This more complex type of homecare requires highly trained clinical staff to support the process and service. The staff providing the clinical service are currently either employed by the provider trust or, perhaps more commonly, by a commercial homecare service company. A considerable amount of attention needs to be given to ensure that all clinical governance arrangements are closely adhered to, including NPSA and other similar guidance.

Low-tech Homecare Medicine and Services

- 3.21 Low-tech homecare will tend to involve oral medication and requiring limited technical support such as standard concordance monitoring from the homecare provider.

General characteristics involved

- 3.22 Homecare medicines delivery and services are predominately provided by the commercial sector. There is evidence of services such as nursing within HPN or dialysis being provided by both the NHS and the commercial sector i.e. homecare provider or manufacturer.
- 3.23 Products are delivered to the patients' home or nominated address via the postal service or van delivery.
- 3.24 Many of the products associated with homecare are non-tariff for PbR purposes as are the homecare services themselves. The consequences of this are picked up separately.
- 3.25 To initiate homecare medicine supply from a homecare medicines delivery service provider:
- A PCT may provide an order
 - An NHS trust may provide on order
 - An NHS trust prescriber may provide an FP10 HP prescription
- 3.26 Operating as a registered pharmacy, the homecare service provider will then dispense the medicine against the order (with it effectively being a private prescription) for supply to the named patient in their own home. When dispensing an FP10 HP prescription the registered pharmacy will also hold an NHS contract for Community Pharmacy Services.

Value, growth and key characteristics of the homecare medicines market

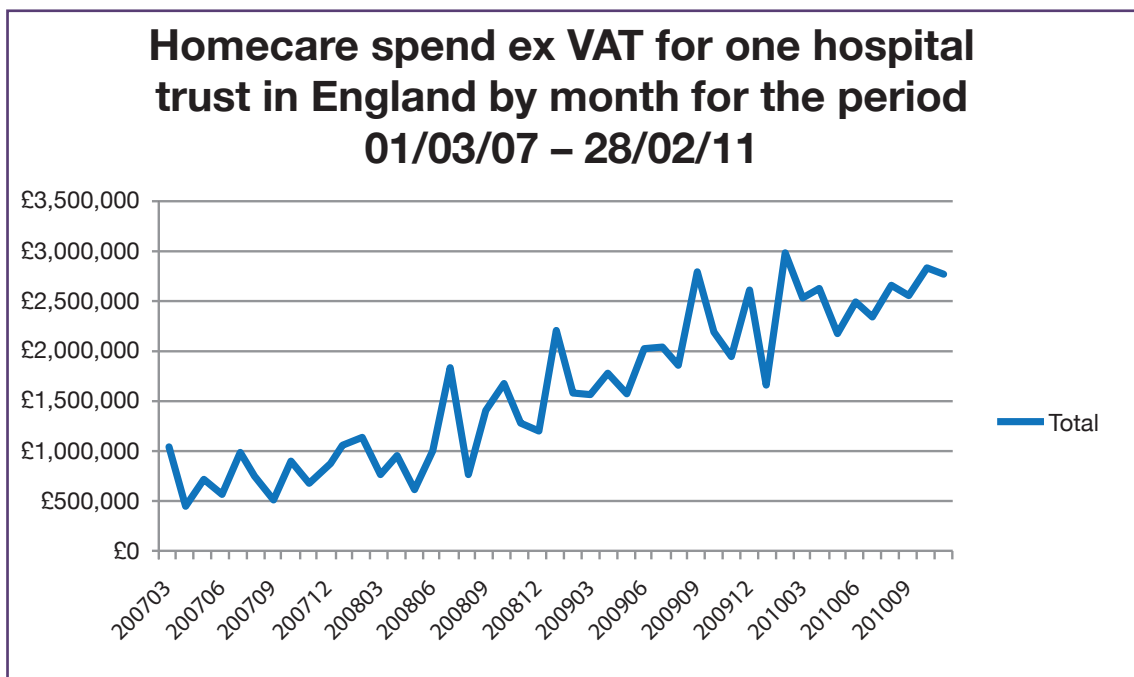
- 3.27 The total value of the NHS homecare medicines market comprises of the value of the medicines plus the value of the associated services.
- 3.28 Unlike the medicines dispensed in primary care, and those supplied by hospital pharmacies in NHS trusts, where information is captured through ePACT and for the most part through hospital pharmacy systems and Pharmex, there is no complete national measure of the homecare medicines market. This is because all the relevant information is not captured through these established systems.
- 3.29 However the NCHA informed the review panel that the UK market, measured by product value, is currently worth £1 billion. The review panel has taken this figure as being one for the whole of the UK and assesses the NHS in England element of this to be worth £800 million if not more.⁶ This figure chimes with CMU projections that it makes using Pharmex.

⁶ Scotland 10%, Northern Ireland 5% and Wales 5%

- 3.30 Without a complete national picture of the market it is difficult to accurately explain the rate of growth in homecare medicine supply.
- 3.31 CMU submitted the following Pharmex analysis to the review panel.

Purchase Year	Homecare Spend (£m)	Non-homecare Spend (£m)	Homecare growth (%)	Non-homecare growth (%)	Overall growth (%)
2007	£176	£1,788			
2008	£249	£2,072	42%	16%	18%
2009	£336	£2,308	35%	11%	14%
2010	£421	£2,395	26%	4%	7%

- 3.32 A pharmex based Trust report separately provided the following picture.



- 3.33 Pharmex reports for homecare medicine reflect a variety of dynamics in capturing spend; for example hospital pharmacists have been active in increasing the capture of homecare medicine through their systems, and NHS Trusts have transferred business to homecare supply and new treatments will have been initiated through this route.
- 3.34 Recognising these points the agreed conclusion is that the homecare medicine market is growing rapidly

- 3.35 This growth can be associated with three characteristics in the market
- NHS trusts continuing to implement EL95/5.
 - Homecare medicines do not incur VAT and this makes some expensive medicines, suitable for homecare supply, more affordable for the NHS.
 - The availability of manufacturer derived schemes offers the NHS homecare medicine supply 'on tap'.
- 3.36 Whilst there is almost total recognition that the priority when redesigning services to patients should be to improve quality of care, in the way that EL95/5 recognised, the following can be factored in to provide a more detailed understanding of why this growth is occurring:

VAT

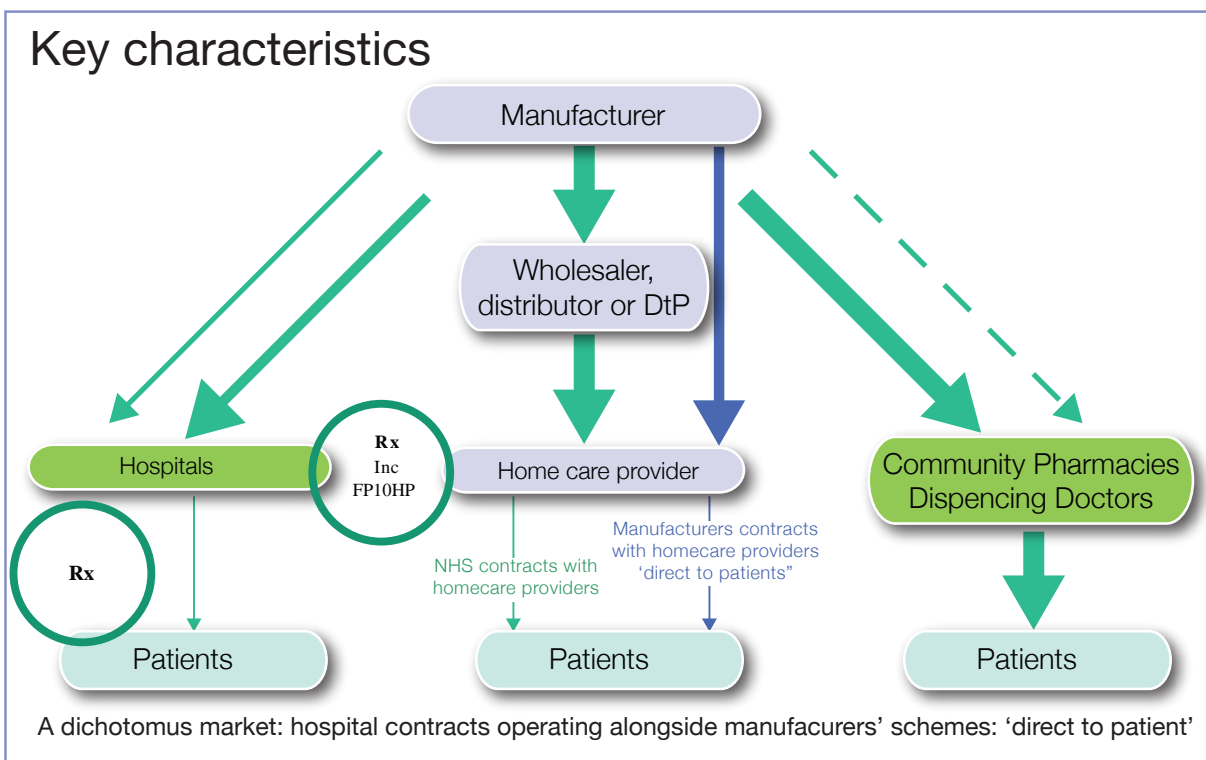
- 3.37 VAT is payable on medicines purchased in secondary care by NHS trusts at the standard rate of 20%.
- 3.38 HMRC have for a long time produced guidance on VAT and medicines supply. This is used locally by local VAT offices. HMRC are in the process of updating a range of guidance. Whilst it is not anticipated any fundamental change to how VAT is applied to medicines supply, there should be greater clarity to reflect a modern approach to pharmacy practice.
- 3.39 Homecare medicines delivery and services do not attract VAT.
- 3.40 By not having to pay VAT on the medicines supplied through the homecare route they become more affordable to the NHS. This feature is of greater significance the higher the price of the medicine, or the total spend on the medicine.
- 3.41 The review panel identified the 'VAT' factor as contributing towards the growth in the homecare medicines delivery and services market.

Manufacturers derived homecare schemes (determined and managed by the product provider and the homecare supplier).

- 3.42 Within PPRS the manufacturers and suppliers of branded medicine are free to place their products onto the UK market at prices they determine.
- 3.43 These prices include the costs of distribution and leave the manufacturers free to determine how they will distribute their medicines.
- 3.44 Against this background manufacturers have introduced direct to pharmacy schemes. These schemes involve manufacturers contracting with distributors and wholesalers as agents, to distribute their medicines to the points of pharmacy purchase. Manufacturers' homecare medicines schemes can be considered an extension to these arrangements, to incorporate dispensing, supply, and sometimes

the provision of equipment, diagnostic services and clinical services to patients in their own homes, within the price the NHS pays for the medicines.

3.45 As a result of the combination of NHS contracts for homecare medicines supply operating alongside the manufacturers' schemes, the homecare medicines market displays a dichotomy.



3.46 The implications of this for the NHS are summarised below.

Arrangement	Homecare provider — NHS choice?	Service fee separate?	Outcome	Overall consideration
Manufacturer schemes	No — determined by manufacturer	No — is included in price of product	Product prices and services cannot be unbundled	Price competition between branded products is limited and the NHS cannot drive for improvements value for money and quality — through competition between service providers
NHS initiated homecare medicine service	Yes — chosen by NHS	Yes — is separate	Prices for product and fees can be separated for invoice	The NHS has scope to chose its service providers based on cost and quality

NHS contracting for homecare medicine

- 3.47 Homecare medicine delivery and services is expanding the ways that the NHS treats and cares for its patients. The NHS currently operates varying models of contracting.
- 3.48 CMU have initiated and adopted the appropriate contracting models to accommodate nationally and regionally commissioned services. In particular focusing on new national frameworks commencing in 2012, to support the HPN, Enzyme Replacement Therapy and Pulmonary Hypertension markets. These frameworks will enable the networks to begin to adopt a common specification and collaboration to ensure value for money, and compliance with current procurement legislation.
- 3.49 NHS trusts have undertaken a limited amount of tendering for homecare medicines. With an estimated £1 billion market, this activity should be being managed within each trust to ensure compliance with local Standing Financial Instruction and compliance with the Official Journal of the European Union (OJEU).
- 3.50 Homecare medicines delivery and services is currently bound and limited to the opportunities open due to a model which has built over time and detailed in the table 3.36.
- 3.51 The medicines which fall into manufacturer schemes are few, however the costs are high.
- 3.52 Whilst the perceived burden is taken away from the NHS, the transparency of product and service is not clear as the two elements i.e. product and service are not separated.
- 3.53 The NHS has either no, or limited choice, of homecare provider to deliver their products to their patients, and limited knowledge of whether it is obtaining value for money.
- 3.54 The NHS to date has no influence over these arrangements, and the process is managed and facilitated between the manufacturer and the homecare provider.
- 3.55 In managing and supporting its development the NHS has to manage homecare medicine arrangements that it has initiated itself, alongside the 'fixed offers' that the manufacturers offer within their schemes.
- 3.56 In the case of the former, the NHS will award a contract for the medicine and then separately tender for the provision of a homecare medicine.

Therapies and conditions associated with homecare medicines

3.57 The following are associated:

- Antibiotics-IV
- Chemotherapy – oral and IV
- Cystic fibrosis
- Dermatology
- Erythropoietin-stimulating agents (ESAs)
- Fertility –assisted conception
- Growth hormone
- HAART (HIV)
- Haemophilia
- Hepatitis B
- Hepatitis C
- Immunoglobulin
- Long-term conditions management, e.g. chronic obstructive pulmonary disease (COPD)
- Multiple sclerosis
- Parenteral nutrition
- Parkinson's disease
- Post transplant — immunosuppressants
- Pulmonary arterial hypertension
- Renal replacement therapy (chronic)
- Rheumatoid arthritis
- Schizophrenia
- Thalassaemia

Appendix D details hospital Pharmex usage*.

Appendix E details other contracting models in operation within the NHS.

Appendix F provides evidence of value by product molecule*.

**Appendix D and F are not included as they contain commercially sensitive information.*



The Challenges facing Homecare Medicines

4

Market issues

- 4.1 One supplier enjoys the 'lions' share of the business measured by product value. **Appendix G** explains the characteristics associated with such dominance. **Appendix H** provides a Pharmex based analysis*.
- 4.2 Associated with this, risks are high for certain providers. Product manufacturers and suppliers will not extend credit to all homecare providers, illustrated case study in **Appendix I**.
- 4.3 Cash flow remains a core focus for this market due to the varying rebate systems operating, and how these are extended to the homecare providers. NHS income may be secure; risks arise because of the sheer value of the products involved. The value and cash flow responsibility for the homecare providers is high.
- 4.4 With the current homecare model providers are bound to pay list price, upon proof of delivery, reimbursement at the contract price is then made.
- 4.5 Risks are high should a manufacturer and product supplier cease trading with a homecare provider. This immediately impacts on the treatment and care of the patients. The choice of homecare provider becomes limited and the NHS is then forced to source alternative homecare arrangements. This can involve:
 - Transfer of patient details to new provider.
 - Ability of the new provider to absorb an increased workload at short notice.
 - Repatriation of patients into the NHS.
- 4.6 'Risks are generated where providers do not have sufficient information on which to base tender responses, e.g. where service users have not provided sufficient detail to inform the tender specifications.' NCHA 18 April 2011.
- 4.7 'Providers are often expected to take risk and liability from issues beyond their reasonable control for example patient omissions or communication failures.' NCHA 18 April 2011.
- 4.8 NHS trusts can be slow in settling their bills.
- 4.9 A manufacturer associated homecare medicine supply with parallel exportation of branded medicines and a service provider also implied this was happening. For the medicines within the NHS (England, secondary care) this practice is rejected, (Dr Keith Ridge letter to the NHS Chief Pharmacists February 2010). If parallel trading is underpinning a homecare medicines business model it implies an unquantified risk.
- 4.10 **Appendix J** provides a copy of Dr Ridge's letter

*Appendix H is not included as it contains commercially sensitive information.

The Challenges facing Homecare Medicines

4.11 The NHS does not manage its homecare business in a consistent way — it is not an easy customer to do business with because of its fragmented nature, failure to use modern technology and the inadequacy of its systems.

4.12 There is a lack of standard contract documentation.

Conclusions

4.13 A rapidly expanding market with high concentrations of business in certain sectors with new entrants and certain sectors demonstrating high/low market concentrations.

4.14 Cash flow for certain homecare medicine providers is unstable, given the arrangements between homecare providers, manufacturers and the NHS around payments.

4.15 A perception of unreasonable risk transfer to the homecare providers from commissioners or acute providers.

4.16 Clunky arrangements to administer homecare medicine supply which are costly, labour intensive and not efficient or effective in some cases.

4.17 Relatively weak contractual, governance and operational control mechanisms.

4.18 Procurement mechanisms need transparency, co-ordination and sensible commercial arrangements.

4.19 Need to see homecare services as part of local health system strategy

Governance

4.20 The review was asked to provide recommendations on what constitutes best practice with respect to the procurement of homecare medicines delivery services including:

- Financial governance
- Clinical governance
- Operational efficiency

4.21 Good governance is delivered through:

- Leadership
- Management
- Relationships
- Systems
- Process

4.22 When these are all properly in place operational performance should follow. The implication of this is that governance and operational performance cannot be separated. This is reflected in the recommendations.

Financial governance

4.23 The procurement of homecare medicines in trusts across the UK may not be fully compliant with local trust Standing Financial Orders and Instructions, and EU procurement law. The typical scenario in some trusts is that homecare is set up for a small number of patients initially, undertaken on an informal ad hoc basis and often within one clinical speciality. Patient numbers then grow (sometimes to the point of multi-million pound turnover) without a formal tender and without appropriate governance arrangements, or performance management of the homecare supplier in place. Even if the homecare service is subsequently tendered, there may not be proper trust-wide collaboration, with different homecare providers being used across different therapy areas.

4.24 In 2005, in absence of national visibility of the homecare medicines market, David Nicholson wrote to NHS Chief Executives, Finance Directors and Chief Pharmacists setting out DH objectives to access homecare data to support PPRS (**Appendix K**). Whilst at the same time DH consultants and CMU engaged with the NHS Trusts and PCT to collect the information in a systemised way. The resulting dialogue, with both finance officers and pharmacists, provided considerable insight into the local management of homecare medicine supply. Some of the key findings from this exercise are summarised below.

CMU and DH conclusions from trawl to collect homecare medicine supply data from the NHS following David Nicholson letter in 2005

4.24.1 There were issues relating to products and purchasing methods

Topic	Issue	Implication
Product	Branded and generics are sometimes mixed by the supplier before delivery and a single charge is made regardless of mix	Spend cannot be separated for branded products as no breakdown is given and varies from patient to patient
Purchasing	Trusts/PCTs purchase the same drug from multiple suppliers but record this as one bundled total for the value for the drug	Difficult to get true cost of drug for analysis
	Service charges are not separated from drug charges in invoices	Cannot get true drug cost for analyses
	Trust/PCTs have a complex discount and rebate process with suppliers/manufacturers	Complex payment system and uncertainty over true price paid
Other common issues	Difficult to Identifying relevant contact/communications between departments	Insufficient resource

The Challenges facing Homecare Medicines

4.24.2 There were limitations extracting data from finance and pharmacy systems

Topic	Issue	Implication
Hospital finance systems	Difficult to access data outside of current financial year as system closes it off	Full dataset missing for year-on-year analysis
	System only records calendar or usually financial year totals	Cannot break spend down into periods for more detailed analysis
Hospital Pharmacy Systems	System stores generic names only and does not differentiate between branded and generics	Spend for branded products cannot be identified
	Some Pharmex submissions by Trusts/PCTs can be inconsistent or drug names misleading	Analysis of data in national system may be inaccurate and incomplete

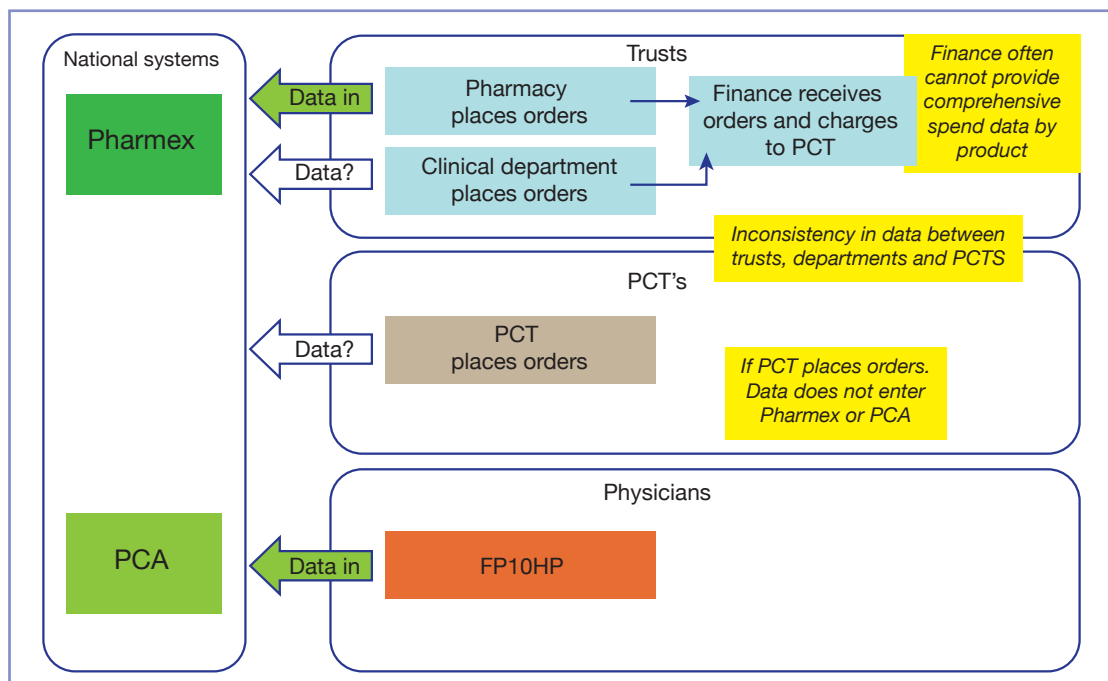
4.24.3 Complications arose from PCT – trust relationship with inconsistent reports of work and financial flows

Topic	Issue	Implication
PCT-Trust Relationship	Drugs are commissioned by trusts but paid for by PCTs	No clear responsibility for data collection leading to double counting or overlooked spend
	A tertiary trust may request invoices are sent to a number of PCTs for homecare services	Potential to miss spend as the trust cannot identify all the PCTs invoices and individual PCTs may not record this

4.24.4 The exercise identified some key issues faced by trusts and PCTs when storing and collecting spend data

Topic	Issue	Implication
Current trust data storage and collection methods	Volume data not recorded as not entered into system	Extracting price data requires manual data input from paper/PDF invoices
	Invoices are not stored in an active database only as paper invoices or PDF format provided by their data base	Manual data input required increasing timescale for reextracting data. Increased likelihood of missing invoices
	No standardisation as departments in the same trust collect data independently using different systems and often collecting different types of data	Some spend may be missed where it spans different departments Complete picture may be missing from trust/PCT if different data submitted by departments

The problems with data flow can be summarised



- 4.25 The fact that significant levels of homecare medicine supply data (30%) was not available through trust pharmacy systems, suggested its management was not being subject to medicines management practices, under the control of the Chief Pharmacists — (definition of Medicines Management: Medicines management in hospitals encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing Informed and desired outcomes of patient care. Source Audit Commission) and the usual financial controls associated with medicine procurement and supply.
- 4.26 Since 2005 hospital pharmacists have orchestrated their efforts to process ordering through their systems. However the review panel detected no evidence that suggested the initial assessment formed in 2005 had changed — and indeed the overall impression was reinforced.
- 4.27 Based on the recognition that there were 'centres of excellence' within the NHS, the steering group invited the Procurement Pharmacist and the Director of Financial Management of The Leeds Teaching Hospitals NHS Trust to explain how they managed homecare medicines, and to relate this to overall performance.
- 4.28 The Procurement Pharmacist explained that his Chief Pharmacist is responsible for all aspects of medicines management for the Trust, including homecare medicines management. The Procurement Pharmacist, Chief Pharmacist, and other pharmacy staff meet with the Director of Financial Management and other finance staff on a bimonthly basis to discuss medicines finance issues, including homecare.

The Challenges facing Homecare Medicines

The Leeds Model: Financial governance

Activity	Perceived National Problem	Leeds Approach
Procurement	Procurement of homecare medicines delivery service in Trusts may not be compliant with local Trust Standing Financial Orders and Instructions and EU procurement law	All Trust homecare medicine related activity complies with local Standing Financial Orders and Instructions and EU procurement law
Audit requirements for prescription-order-invoice-delivery proof	<p>Some Acute Trusts are prescribing homecare medicines, and invoices are being sent directly to the commissioning organisation (e.g. PCT)</p> <p>Best practice requires an order to be raised on the pharmacy IT system following receipt of a homecare prescription.</p> <p>Once an invoice and a delivery proof is received by the Trust's pharmacy department prescription/order/invoice and delivery proof should be checked against each other, then cleared for payment if correct</p>	<p>The Trust is managing the clinical care of the patient and therefore provides the homecare medicines prescription.</p> <p>The Trust therefore receives and pays the invoice from the homecare supplier</p> <p>The trust operates this model of best practice for all homecare medicine management activity that it is associated with (see also the section below on "reporting and monitoring medicines spend)</p>
Reporting and monitoring medicines spend	<p>The reporting of spend on homecare medicines is variable across Trusts</p> <p>There is variable coordination between pharmacy and finance departments in Trusts, strategically and operationally on homecare medicines delivery and services</p> <p>Trusts have variable pharmacy management of homecare medicines delivery and services based on the orders and invoices being managed on a pharmacy IT system</p> <p>Some Trusts may not be using homecare services due to the administrative burden associated with them for the provider Trust, when the financial benefits appear to be solely for the commissioning Trust</p> <p>There may be variable reference in tender documents and service specifications to the homecare supplier's duties to provide data and management information (including financial information) to the Trust</p>	<p>Homecare medicines delivery and services spend is reported regularly within the Trust, alongside current reporting mechanisms for identifying and managing medicines spend</p> <p>There is strategic and operational liaison on a regular basis between pharmacy and finance departments on homecare medicines delivery and services</p> <p>The Trust pharmacy IT system is used to manage all Trust homecare medicines except Clotting Factors</p> <p>The Trust has entered into discussions with its commissioners to identify the projected savings associated with moving to homecare supply on excluded from tariff medicines, with the aim of proposing a share of the overall savings, which in part would meet the Trust's pharmacy administrative needs.</p> <p>The Trust ensures that tender documents and service specifications include references to the homecare supplier's duties to provide data and management information (including financial information) to the Trust. The Trust ensures that the NHMC guidance documents are used during their tender activity.</p>

Clinical governance

- 4.29 All Chief Pharmacists not capturing all homecare medicine supply within their trust role of medicines management.
- 4.30 The NHS may find itself funding its own clinical services, to support homecare medicine supply, even when these are available within the NHS price for a medicine as part of manufacturer derived scheme. This reflects a disparity of confidence (NHS service versus external provider service).
- 4.31 A homecare medicine patient may receive homecare medicine supply from one provider for one therapy and from another provider for another therapy.
- 4.32 Clinical support for homecare medicine supply is not associated with the same specialism found in acute in patients. That is Acute Trust renal nurses and Acute Trust oncology nurses and the associated knowledge and experience this brings versus a perception that a homecare provider nurse might have to deal with both oncology and renal products.
- 4.33 Alongside recognition of the role of the Care Quality Commission, no clear understanding was given as to how this role was fulfilled, or standards met, with regard to homecare medicine supply.
- 4.34 A shared understanding of clinical issues relating to homecare medicine supply across acute trust nurse specialist, but no clear recognition and agreement as to how clinical standards were met either for individual trusts or across therapies.
- 4.35 A requirement for service providers to recognise NHS values with regard to the care of patients.
- 4.36 A problem of homecare service providers recruiting clinical staff.
- 4.37 Consultants delegating clinical decisions and management without a sufficient understanding of what was involved in homecare medicines supply.
- 4.38 A mixture of standards applying to homecare medicine supply — clinical and pharmaceutical — with no distinct visibility as to how these were being met from an NHS perspective.
- 4.39 The management of homecare medicine supply can be fragmented within a trust leading to both poor financial and clinical governance.

The Challenges facing Homecare Medicines

The Leeds Model: Clinical governance

Activity	Perceived National Problem	Leeds Approach
Clinical governance	There is variation in applying the same clinical governance frameworks to homecare medicines that are applied to medicines used within Trusts. In some trusts this may be left to the individual clinical directorates with no pharmacy involvement.	The Trust applies the same clinical governance frameworks to homecare medicines delivery and services that it applies to medicines used within the Trust
	Policies and procedures that are in place for use within the Trusts may not be being applied to homecare medicines when contracted out	The Trust's policies and procedures that are relevant to the care of homecare patients are applied by the Trust to its homecare medicines providers
	Incident reporting and complaints procedures that are in place and used within Trusts are not consistently used for homecare medicines delivery and services	The Trust seeks to ensure that incident reporting and complaints procedures are in place for homecare medicines providers
	There is variable quality assurance of homecare suppliers	The Trust ensures its homecare medicines providers are audited for quality assurance purposes, with audit reports and ongoing actions fed back to the Trust
	There is variable quality assurance of unlicensed medicines homecare suppliers are supplying to the NHS (e.g. compounded intravenous nutrition, compounded intravenous antibiotics)	There are plans in place to ensure that all unlicensed medicines supplied as part of a homecare medicines delivery and services are assessed for quality assurance purposes as part of future tender processes
	There is variable risk assessment of proposed/new homecare medicines schemes undertaken by Trusts, to help identify potential governance issues	The Trust undertakes assessments of proposed and new homecare medicines schemes to identify and manage potential governance issues
	There may be variable reference to clinical governance in tender documents and specifications	The Trust ensures that tender documents and specifications for homecare medicines contain reference to clinical governance

4.40 Leeds' operational performance can be seen to flow from its governance arrangements through to the allocation of resource, implementation of process and the use of its pharmacy system (integrated into finance and commissioning) as best as it is able within the limitation of the system.

The Leeds Model: Operational efficiency

Activity	Perceived National Problem	Leeds Approach
Operational efficiency	Trusts' Clinical Directorates may be managing and operating homecare medicines independently of Medicines Management and Pharmacy	The Trust's Chief Pharmacist (Clinical Director for Medicines Management & Pharmacy) is responsible for the management of homecare medicines delivery and services.
	In Trusts where individual Clinical Directorates are responsible for the management of homecare medicines delivery and services, the administration of the homecare services are likely to be less efficient than a centralised service delivered by Medicines Management & Pharmacy	The Trust achieves operational efficiency through the centralised management of homecare medicines administration by Medicines Management & Pharmacy
	There is minimal use of electronic prescribing for homecare medicines	The Trust has plans to develop the use of electronic prescribing for homecare medicines in its e-prescribing programme.
	There appears to be minimal use of electronic ordering and invoicing for homecare medicines	The Trust has plans to develop the use of electronic ordering and invoicing for homecare medicines to bring it in line with the electronic procurement of the majority of medicines

- 4.41 The Leeds case study demonstrates that proper management of homecare medicines involves investment in systems and processes. **Appendix L** presents Leeds model of Medicines Management
- 4.42 In an NHS study it was calculated that £50 per homecare patient per annum was required to fund the pharmacy administration of homecare medicines services.
- 4.43 **Appendix M** explains the rationale and methodology used. It is possible that in a large trust that administration costs per patient would be lower and in a small trust higher because of economies of scale.
- 4.44 Homecare medicine supply involves product and service costs. Hospital pharmacy systems (particularly JAC and Ascribe) are not able to process the two elements side by side. And so whilst the systems are not perfect expertise, ingenuity and effort is required to make the best use of them so their use to manage homecare is not necessarily easy.
- 4.45 The NHS has undertaken its own survey of the use of hospital pharmacy systems to manage homecare.

The Challenges facing Homecare Medicines

- 4.46 Both JAC and Ascribe have announced that they will introduce developments to enable pharmacy departments to manage homecare medicine properly.
- 4.47 The homecare providers believe that such development should be undertaken in association with themselves as well as the NHS.
- 4.48 The NHS users of particular pharmacy systems have to work with the system providers to agree prioritisation. Different trusts use different versions of the same system. The system providers offer some developments as enhancements to all users within their service contracts (depending on the version operated). For other developments the trust has to purchase the development.
- 4.49 Trusts do not use the same product descriptions.
- 4.50 Pharmacy/finance interfaces are variable e.g. poor levels of electronic invoicing.
- 4.51 Electronic ordering is not used for homecare medicine (as is the case with normal medicine procurement).
- 4.52 While to some degree the ability of the systems to manage homecare medicine supply already exist, and the systems are seeking to enable this to be done properly; it is difficult to envisage rapid NHS implementation without some coordinated support.
- 4.53 The NHS does not manage homecare medicine, and capture associated information in a systemised way and as a result, it cannot provide the DH with national visibility of homecare medicines for PPRS purposes (in contrast to the community market that it measures through e-PACT and the hospital market measured through Pharmex).

Governance and operational performance - conclusions

- 4.54 Chief Pharmacists are not always involved in homecare medicine and without this engagement acute trusts cannot maintain and improve control in this key medicines management area.
- 4.55 Internal acute sector governance processes, in many cases, lack rigour, transparency, clinical control and engagement. Major improvements are needed to ensure that these are met, together with cost effectiveness of homecare medicine delivery and monitoring.
- 4.56 High transaction costs in operating homecare medicines given the weak use of IT and involving processes between hospital pharmacy, finance departments and PCT's.
- 4.57 There is a lack of accreditation system for homecare medicines service suppliers, which set minimum standards which the NHS should expect from a competent supplier to act in patient's best interests.

- 4.58 The lack of mechanisms to track homecare medicines could impact on the NHS seeing full value for money from the Department of Health's Pharmaceutical Price Regulation Scheme.
- 4.59 The role of Medical and Nursing Directors and Trust Chief Pharmacists needs to be strengthened in hospitals and across commissioners, to operate better homecare medicines.
- 4.60 The current mechanisms for ordering homecare medicines needs greater control, i.e. via designated pharmacists and pharmacies, but the role of the Chief Pharmacist in trusts needs change to move to services not just product supply with greater involvement of Trust Medical and Nursing Directors.
- 4.61 The current arrangements for homecare providers to work to the acute hospital customer are weak, and governance systems are not aligned and integrated into a single system.

Collaboration across organisations

- 4.62 Current procurement of branded and generic medicines within secondary care involves collaboration between Trusts, an approach that has worked well and delivered benefits over a number of years. A similar coherency is not reflected in any NHS recognised strategy for the procurement of homecare medicine. This can be associated with a lack of market structure associated with this route of supply.
- 4.63 Opportunities for collaborative procurement within homecare medicines have been previously highlighted in **Chapter 3**.
- 4.64 The relationships between commissioners and providers is critical. They are also variable. They range from being near perfect partnerships at one end of the spectrum, to antagonistic at the other.
- 4.65 Non-tariff Payment by Result medicines represent 60% of acute hospital medicine spend. There is an overlap of individual high cost non-tariff medicines and homecare medicine supply. Homecare supply is itself non-tariff.
- 4.66 A common theme within the NHS is that 'NHS trusts (providers) can invest all the effort in securing best value for non tariff PbR medicines with all the benefit going to commissioners'. This view encompasses homecare medicine supply. Some regions have addressed this issue with thorough agreements in place between the commissioner and the providers to incentivise the providers to secure best value based on reward for effort.
- 4.67 Opportunities increase where there is alignment between commissioning, implementation of homecare supply and review of clinical practice for example a switch from intravenous to oral medication.
- 4.68 South Central provides a case study of how this can be managed.

NHS South Central Framework for the Management of High Cost Drugs excluded from the PbR tariff including homecare medicine supply

Until recently, commissioners and providers have been left to develop local agreements for the use and funding of such medicines and their associated supply in addition to the tariff. The high cost drugs exclusion list only describes how the medicines should be reimbursed; it does not describe how the use of that medicine will or should be commissioned. These decisions are usually made at Local Prescribing Committees at which both providers and commissioners are represented.

In 2009, Chief Pharmacists and PCT Heads of Medicines Management agreed to a set of principles relating to PbR excluded drugs but progress in releasing savings has not been universal. This arose in part because whilst the providers had to make all the effort to generate benefits the benefits accrued to the providers.

Recognising this issue South Central Chief Executives acknowledged the issues concerned with PbR excluded drug costs and asked that the Medicines Use and Procurement QIPP devise a framework to support primary and secondary care Trusts working in collaboration to address the area and realise the efficiencies. High cost homecare delivery medicines were scoped for inclusion as were the homecare medicines services them selves.

As a result of interactive and collaborative working between themselves the commissioners and providers across the geography have agreed a list of criteria for scoping an approach and have agreed incentive payments options through which the efforts required by providers to generate benefits and set up appropriate management and control systems are recognised and rewarded.

By all parties agreeing this approach south central has now mobilised a programme that combines both a clinical review of cost effective prescribing with the ability to deliver homecare medicine supply through established framework agreements for these services.

Clare Howard

Pharmaceutical Adviser
NHS South Central

Conclusions – collaboration across organisations

- 4.69 The collaborative approach for homecare medicines delivery and services needs better NHS Trust and commissioning alignment to improve patient services.
- 4.70 Engagement of all varying stakeholders including clinicians and patients to ensure compliance, commitment and uptake of the service.
- 4.71 Need to ensure the reduction of unnecessary administrative burdens associated with homecare.
- 4.72 Incentivisation of homecare providers to:
- Reduce transaction costs
 - Improve cost of whole healthcare system
 - Management of homecare demand
 - Improve patient services
- 4.73 This incentivisation, to achieve the stated aims, will only occur if the NHS engages with the homecare providers to positively redesign patient care, through the opportunities that homecare medicine offers, through collaborative working relationships.
- 4.74 National or regional collaboration needs to incentivise NHS providers and commissioners, to collaborate to maximise opportunities and benefits.

Patient safety

- 4.75 Concerns around the safe and effective use of medicines in the acute sector are well documented, along with the risks associated with administration error and the impact of missed doses.
- 4.76 There is no similar and readily available assessment of the problems in homecare medicine in the UK, and the NHS does not have a strategy in place to address them. This contrasts with the medicines management agenda within the acute sector.

Patient involvement

- 4.77 There are limited examples in England of where patients play a part in monitoring the service provided by homecare medicines service providers, alongside Trust Pharmacists, Trust Medical Directors and Directors of Nursing, to secure and improve homecare medicines service performance.

Patient involvement – conclusions

- 4.78 Patient centred solutions could be improved around delivery, storage, conformance to medicines and quality monitoring of the service.
- 4.79 Levels of wastage of homecare administered therapies could be reduced.
- 4.80 There are problems with current patient equity and access to homecare medicines delivery and services for patients.



The Vision for the Future

5

- 5.1 Patients do not hold back in expressing the benefits they experience from homecare medicine. At the same time, homecare medicine is enabling NHS clinicians and managers to redesign patient care pathways in ways that are providing the NHS with opportunities to increase the value for money that it provides taxpayers with, in line with Government policies.
- 5.2 However, to maximise these opportunities to the full — for both patients and taxpayers - all parties involved in homecare medicine — patients, clinicians, managers and providers - will have to contribute towards its strategic development.
- 5.3 These individual contributions in themselves will not deliver the future vision for homecare medicine. Rather each must be seen as contributing synergistically towards a comprehensive strategy with all the parties' involved making equal contribution.
- 5.4 More stability for new and existing homecare providers by collaborative purchasing.
- 5.5 Stable contractual frameworks which are of sufficient duration to secure best value for patients and taxpayers.
- 5.6 Homecare suppliers should be prepared to take proportionate risks to invest in new technology, service levels and cost efficacy.
- 5.7 Need to consider separating homecare services and supplies of medicines.
- 5.8 Integrated governance with NHS provider as the customer.
- 5.9 Homecare providers and NHS should have a set of industry standards which cover major areas of governance, operational control and approaches.
- 5.10 Kite mark or similar accreditation for individual homecare providers to enter into NHS contacts **Appendix N** provides some thoughts on this approach.
- 5.11 In addition to a kite mark or similar accreditation for NHS purposes, the same approach for individual pharmaceutical manufacturers' schemes should be applied. This would give NHS staff an assurance that the agreement between the manufacturer and the homecare provider was a fair and balanced view point. It would also give homecare providers the assurance that individual Trusts wouldn't make wholesale changes to the content. The mechanism to achieve this would be engagement with NHS and industry groups.

Developing Acute Providers

Strengthening the role of key Trust staff

- 5.12 The evidence received by the review raised a number of issues around the need to clarify and strengthen the roles of key trust staff as outlined in chapter 4.
- 5.13 The supply of homecare medicines through arrangements with homecare suppliers remains the responsibility of the Trust Chief Pharmacist. In considering this, and the supply of assisted healthcare services, it is clear that at trust level there is a need for a responsible authorised officer to be designated to undertake the oversight and accountability of homecare medicines, commissioned by the trust as the 'authorised body' requesting homecare. Given the statutory and regulatory accountability of trust Chief Pharmacists for the supply, prescribing and management of medicines, it is felt appropriate that they should be the 'authorised officer' with the 'authorised body' to take responsibility for all aspects of homecare medicines. This will require assessment of their role, and the necessary training and development to be put in place.
- 5.14 The role of this authorised officer will be to:
- Set a strategy for homecare medicines within the Trust working with commissioners, to maximise the value to patients and the health system. This strategy should consider the types of clinical services which are relevant and appropriate to homecare; the type of service which will be required and the arrangements need to secure effective homecare provision. One can envisage this setting out a broad strategic direction of what will be delivered, when it will occur and how it will be secured over a minimum 5-year period. This will need to be based on close collaboration working with patient groups, commissioners, hospital clinicians, nurses and professions aligned to medicines and the executive level responsible for governance. This strategy should be signed off with CEOs and Commissioning CEOs after discussion with local drug and therapeutics committees, which bring Hospital Doctors and GPs together with Chief Pharmacists.
 - With the overarching strategy the Trust Chief Pharmacist should prepare an annual programme for homecare medicines delivery and services, which will cover new and existing services and how these are to be maintained, changed or improved. These need to be consulted on with drugs and therapeutics committees, and approved by Trust and Commissioner CEOs.
 - The role of the Nurse and Medical Directors needs to be more explicitly identified, for them to work with trust Chief Pharmacists on the identification of patient cohorts, the most appropriate pathway for homecare medicines, and the specific governance mechanisms required to give assurance and maintain high quality care to patients.
 - The delivery of effective information and financial systems to ensure the timely, accurate and reliable processing of homecare medicines supply, prescribing, patient tracking and monitoring mechanisms using the current pharmacy system.

- The responsibility for certain patient feeds should transfer to planning management such as HPN.
- Ensuring there are clear responsibilities set for General Practitioners, patients, Trust Clinicians and Pharmacists for the care pathway.

5.15 Ensure governance arrangements in relation to patient safety state aspects of care for which the following are responsible

- Hospital
- Homecare Company
- GP
- Health professionals
- Patient
- Availability of backup advice and support

5.16 It should explain:

- How will the treatment plan be communicated to the patient, homecare company, GP other healthcare providers.
- How will the initial prescription and repeat prescriptions be produced, and who will check this prescription in the Trust before communicating to the home healthcare company.
- What level of clinical checking of the prescription and patient will the home healthcare company undertake.
- How will the clinical and laboratory monitoring be undertaken.
- What are the arrangements for patient safety incident reporting, performance monitoring and outcome monitoring?

All these reports should be shared with the Trust and then the NRLS.

The Trust should have a formal way of reviewing these reports and taking necessary action.

5.17 The home healthcare company should also provide to the Trust electronic copies of medicines policies, control of infection policies, and other policies impacting on patient safety and clinical effectiveness.

Improving collaboration between organisations locally

5.18 There needs to be a clearer understanding of which homecare medicines are procured at a national or regional level, to maximise value for money and ensure safe, effective and responsive services. There will need to be work undertaken to specify these levels of procurement, involving NHS and CMU colleagues consulting with industry.

- 5.19 Once the appropriate level of procurement has been defined, there needs to be developed a national NHS framework agreement for homecare medicines delivery and services, with clear common specifications which can be tailored for local use.
- 5.20 In developing a national NHS framework agreement, it is envisaged that these will cover standard NHS terms and conditions required of homecare organisations and the NHS. Ensure a minimum set of standards which homecare providers will meet, in order to provide homecare medicines to the NHS.
- 5.21 At a national or regional level, there will be a need for commissioner and provider to agree a simple formula on how savings from procuring homecare medicines can be shared appropriately, with lists covered by the provider. There are examples already of best practice in county.
- 5.22 **Appendix O*** provides a starting point for accessing commercial opportunities within the homecare medicines market. Local collaborative procurement organisations should use this information and the recommendations within this report to scope and target commercial opportunities as a matter of extreme urgency, as part of their QIPP programme.

Supplier risk

- 5.23 Providers should ensure precautions are taken to manage commercial performance and risk, by familiarising itself with publicly available information relating to homecare providers trading positions.
- 5.24 CMU to support NHS assessment of the publicly available information through links on their website
- 5.25 CMU to develop the required expertise to objectively assess and advise the NHS on the use of this information.
- 5.26 Manufacturers to work with CMU and the NHS to establish an appropriate cash flow model
- o Contract price is charged at the start of any contract
 - o Explore consignment stocking

Better incentives for everyone

- 5.27 Fundamentally, there is a need to ensure a modern commercial partnering arrangement existing between the 'authorised body', i.e. the NHS Trust, and the homecare organisation to continue to allow services to constantly improve.
- 5.28 The types of incentives fall into a number of areas:
- Reducing demand or growth for homecare medicines delivery and services
 - Integrating homecare medicines into a chronic or stable condition service
 - Increasing the involvement of patients in setting and operating homecare medicines.

**Appendix O is not included as it contains commercially sensitive information.*

- 5.29 The industry supplier and the trust should commit to a level of patient demand over the contract period, plus commitment based contracting. This provides an incentive to the homecare provider, to manage more effectively their cost base, and plan well ahead. In return, the Trust should expect the homecare provider to regularly review patients with the hospital team, to establish which patients can leave the programme, and receive care that is different based on their clinical condition, or in an alternative setting e.g. community pharmacy. The homecare provider and the trust can then agree whether the programme then uses costs to be released to recruit more patients, to replace those leaving, or savings are shared.
- 5.30 NHS trusts and homecare providers should be encouraged to develop more synergy to deliver homecare models, which could see NHS staff seconded doing the work on a further part-time basis, to enable the integration of care services more seamlessly with the NHS Trust and the homecare provider, and reduce costs for either party. There will be further synergies if the service is considered against the wider roles undertaken across the health system.
- 5.31 Going forward, the technological know-how is already available, or potentially available, to develop more effective ways in which patients can:
- Confirm the delivery of their homecare.
 - Express whether they are receiving it to the level expected and their satisfaction with this
 - Use systems to communicate comments and observations on their management or systems; complete patient based outcomes or process reports and report patient incidents.
- 5.32 The Trusts and homecare supplier, in agreeing contracts, need to ensure the service delivers this technology, to improve the service to the patient in the modern age, and enable the NHS and homecare providers to reduce their transaction costs. Should homecare provider culture to innovate above a certain industry standard level, then they should be incentivised formally to do so if this releases resources across the NHS Trust or pathway, which can be secured.
- 5.33 Patients also need to be engaged much earlier in the design of homecare services. Commissioners and providers, in setting strategies for homecare in the context of their desired patient pathways, need to involve patients who are experts in their condition, in helping to determine service standards and required service levels, and many other aspects of the service such as communication. There needs to be much more of a patient partnership in selecting homecare providers, and being involved in the review of the performance of the service. The need to look at routine reviews inviting patients, hospital clinicians and the homecare supplier should occur as a minimum.

Delivery for commissioners

- 5.34 In the future there needs to be a focus in collaboration between commissioners and the provider who is responsible for the homecare service. This needs to be at a strategic as well as operational level.
- 5.35 Naturally, commissioners in considering the homecare strategy formulated by the authorised provider need to establish how homecare is relevant to the delivery of their strategy, for a range of clinical stable conditions which they are commissioning services for within their localities. Increasingly commissioners need to work with providers at looking at the considerable benefit across a whole lifecycle cost of a chronic, or stable condition, that homecare may offer.
- 5.36 This approach would see QIPP savings for commissioners. There will be a need, using the shared savings formula, to ensure providers would be suitably supported in the overhead costs, absorption for such service change if service moved to a different form of delivery and they were left with standard fixed costs.
- 5.37 Finally, commissioners should work with provider Trust Pharmacists to consider a three-to-five-year strategy, of how they should consider non-tariff drugs supply moving to homecare alternatives, to enable effective release of costs to the commissioner using, again, a standard savings sharing formula.

Case Study: Clatterbridge Centre for Oncology NHS Foundation Trust

There are obvious financial costs to running and managing homecare schemes in partnership arrangements with the private sector.

There are also hidden costs associated with validating clinical governance arrangements.

NHS organisations cannot get any experience of using directly employed staff to treat patients under the current VAT arrangements without incurring additional costs.

In providing homecare schemes it is not clear whether VAT savings should remain with the provider Trust, commissioner or be split between the two. Practice varies across the UK, and is also a factor to be considered when examining local practice.

Drug Specific Schemes

Clatterbridge has had experience of a manufacturer specific homecare service for Topotecan a number of years ago. This is a second/third line chemotherapy option for ovarian cancer. Inequity came in when patients with the same diagnosis but on a different (lower cost) regime were not offered a homecare service as this would have incurred additional costs to the Trust and Commissioners.

Inequity for patients

Current homecare schemes for cancer patients focus on the high cost treatments. It is the VAT differences that drive the use of homecare and the cost of the medicine, rather than the needs of the patient. Homecare providers have attempted to address this inequity by offering services where a proportion of low cost medicines are delivered offset by 'profit' on the delivery of high cost drugs. Although this goes some way to providing fairer services, the proportion of low cost medicines that can be given at home is low.

Inequity for providers

Under the current VAT arrangements, NHS Trusts have to either look at becoming Social Enterprises or setting up subsidiary companies within organisations to be able to fund homecare schemes. At the moment it is not a 'level playing field' in the homecare market. If the NHS was able to deliver homecare services itself and gain experience in this area, this could lead to:

- Increased competition would drive quality of service
- The hidden costs of managing a partnership agreement would be reduced, as a directly managed service would allow reduced administration costs.
- The NHS staff would gain experience of delivering care at home and ultimately would result in a better patient pathway.
- In the case of oncology patients the NHS would be able to deliver additional treatments at home as compared to the private sector as a 'profit' would not be taken, and a greater proportion of lower cost drugs could be delivered. The VAT differences could be used to target greatest patient need rather than be drug specific, although of course, high cost drugs would still need to be delivered at home.

Helen Clark
Chief Pharmacist

Making it better for patients

- 5.38 Whilst for a particular therapy, homecare medicine might be appropriate for most patients, it might not be suitable for all of them. For example HIV patients may not wish their family members to know they are HIV positive, and prefer to collect their medicines from either an acute trust, or a community pharmacy.
- 5.39 Patients should therefore be able to enjoy greater choice than they can at present.
- 5.40 The patient is central to homecare medicine. Patients express the benefits of homecare medicine; however, they have to deal with different parties on the same issue, and are not experts in medicine supply management.
- 5.41 Patients should benefit from a 'customer charter' that sets out what they should expect from both the NHS trust that is responsible for initiating the prescribing of their medicines, and the homecare provider that dispenses and supplies them, and provides associated services. This will ensure the patient knows what to expect from homecare medicine, and how to deal with problems when they occur.
- 5.42 With patients aware of what to expect from homecare medicine through this customer charter, they will recognise their responsibilities, and be empowered to monitor the performance of the services they receive through customer satisfaction.
- 5.43 To support the customer charter, to increase their choice and to become engaged in monitoring the provision of services, the NHS, both commissioners and providers, must involve patients in strategically developing, planning, and ultimately marketing homecare medicine contracts.



National Homecare Medicines Committee (NHMC)

6

- 6.1 The steering groups intention was to avoid duplication of the work undertaken by National Homecare Medicines Committee (NHMC), and to give the committee a platform to ensure the documentation and developments already produced gained greater visibility, to support the NHS in future strategy planning.
- 6.2 The NHMC reports to NPSG and PMSG and was formed in 2005 to develop appropriate systems, policies and procedures in order to assist service users, service providers and patients.
- 6.3 There have been many outputs from the NHMC to date which have been developed to support this rapidly growing market.
- 6.4 Development of universally agreed NHS specification documents that can act as a comprehensive template, to assist in the standardisation of practice for NHS service users, particularly when tendering for homecare services. These documents were produced in consultation with CMU, Pharmacists, PMSG members, Hubs, NCHA and ABPI members to ensure their robustness and support of all key stakeholders.
- 6.5 Development of a policy framework for Chief Pharmacists to use when considering the introduction of homecare services in their local trusts.
- 6.6 Production of governance models for change management, which is intended to ensure seamless transition between homecare providers as contracts change.
- 6.7 Provision of commercial market intelligence such as 'supplier profiles'.
- 6.8 Development of supplier homecare audits tools to monitor supplier performance. This involves a regional QA programme of homecare audits established.
- 6.9 Development and early stage analysis of homecare products and therapies, being delivered within the homecare setting.
- 6.10 Development of a NHS generic 'patient registration' form.
- 6.11 Development of a 'business case' model for senior pharmacy managers, to support the funding and development of homecare at a local level.
- 6.12 GPhC engagement to support professional issues, such as the assembly line dispensing process, arms length counselling advice to patients.
- 6.13 Homecare data collection programme which is intended to drive change and practice at a local level. A standard data collection template developed.

- 6.14 Development of generic homecare service KPIs.
- 6.15 Development of a generic patient satisfaction questionnaire for service delivery.
- 6.16 Working towards a national NHS complaints and adverse incidents procedure.
- 6.17 Development of generic award criteria for homecare service contracts.
- 6.18 Creating an environment to develop e-homecare, so that there could be an increase in commercial transaction efficiency between homecare providers and the NHS.
- 6.19 Monitoring the market to try and ensure compliance with appropriate ethical and commercial standards.
- 6.20 The NHMC has good representation from the NHS in the form of PCT Pharmacists, Hospital Procurement Pharmacists, CMU category team, Senior Pharmacy Managers, a Regional QA Pharmacist, Specialised Commissioning, Nursing, RPS & GPhC, representation from the National Clinical Homecare Association (NCHA) and chair of the ABPI homecare Committee.
- 6.21 The success of the NHMC has been due to close collaboration with external agencies, so that there can be the widest consideration as to how homecare medicines delivery and services fits into the changing NHS market. In particular, the NHMC has close communication and relationship with two key stakeholders, the ABPI homecare group and the NCHA. Support from these two organisations has assisted much of the development in practice that has been reached today. A marketing strategy has been developed to try and raise the profile of the committee and their outputs, in the form of communication tools such as a website, newsletter and bi-annual conference.

Documents can be found at <http://cmu.dh.gov.uk>



Appendices

7

Appendix A



Commercial Medicines Unit

Dear

DH sponsored review of the NHS Homecare Medicines in England

The supply of hospital prescribed medicines direct to patients in their own homes is relatively new. Its correct operational management presents challenges to both the NHS and its commercial partners. The market is expanding and arrangements will have to adapt and develop within a rapidly changing healthcare environment.

To ensure that the Department of Health (DH) fully understands the implications for both patients and the NHS, DH have invited Mark Hackett, CEO, Southampton University Hospitals NHS Trust, to lead a rapid review of Homecare Medicine Supply to consider the current operational arrangements and its future for the best value for patients, the NHS and the provider market.

Mark's terms of reference are attached for your information and we anticipate that sometime in the coming weeks he will begin to set out his thinking and create opportunities for you to submit your views to support his task which needs to be completed for the NHS by 31st March 2011.

Any immediate enquiries should be directed to: homecare@cmu.nhs.uk

Yours

A handwritten signature in black ink, appearing to read 'C Theaker'.

Chris Theaker
General Manager
NHS Commercial Medicines Unit
Procurement, Investment and Commercial Division
Department of Health

Homecare Medicine Review Group: Terms of reference

Status and overall aims

Dr Keith Ridge, on behalf of the National Pharmacy Supply Group (NPSG) and the Commercial Medicines Unit (CMU), has sponsored an NHS Trust Chief Executive to lead a working group to review information and evidence relating to homecare medicines.

The Chief Executive will provide the DH with advice to support the development of policy and make recommendations to the NHS concerning collaborative working and operational management, across clinical, pharmacy, commercial and finance disciplines.

The output of the working group will be reported to Dr Keith Ridge and Peter Coates.

The work will commence October 2010, reporting March 2011.

Background

In simplistic terms, two routes of supply determine the way that the majority of NHS patients get their medicines:

- In secondary care locally managed NHS hospital pharmacy services supply medicines purchased against their CMU, regional purchasing group and local Trust contracts
- In primary care dispensing contractors (pharmacy contractors or dispensing doctors) source and purchased medicines and appliances that they then dispensed against NHS (FP10) prescriptions. They are operating under the NHS (Pharmaceutical Services) Regulations 2005 and the Drug Tariff, a Secretary of State Determination outlines what these dispensing contractors will be paid for the products supplied as part of providing pharmaceutical services. In the case of pharmacies, the Drug Tariff also outlines the fees and allowances they will be paid for providing those services, while dispensing doctors are paid for services provided in accordance with the Statement of Financial Entitlement (SFE).

In 1995 the DH formally confirmed a third route of supply 'Purchasing high-tech healthcare at home'. This has subsequently been developed to include both high and low technologies — products and services — and is now referred to as homecare.

Definition of homecare:

A medicine homecare delivery service can be described as one that delivers ongoing medicine supplies and where necessary associated care, initiated by a hospital prescriber, direct to a patient's home with their consent. The purpose of the homecare delivery service is to improve patient care and choice for their clinical treatments.

Since 1995, the value of this additional route of supply has grown exponentially. It is now thought to have an annual value of around £1 billion against NHS secondary care expenditure on medicines of £3.2 billion

This growth has been driven, either individually or in combination, as a result of:

- Meeting the legitimate healthcare needs of patients
- VAT savings

- Manufacturer imposed direct to patient supply

As a market, homecare reflects a hybrid of the characteristics associated with hospital and community supply. It appears to lack consistency across products, therapies and service provision; it is also associated with variable and sometimes weak governance within the NHS.

Against this background, there is growing recognition of the benefits of treating cancer and end of life patients, for example, in their own homes.

If this agenda is to develop appropriately it is essential that the arrangements associated with the supply and administration of medicines are robust and fit for purpose in terms of being safe and appropriate for patient care as well as representing value for money for taxpayers. These attributes can only be demonstrated if the arrangements are operating in a transparent, measurable framework.

Appendix 1 sets out further background of procurement organisation for medicines.

Objectives

In achieving the objectives below the review group will need to understand the homecare market, be aware of models within the EU, understand any links/implications to service provision under the Pharmaceutical Service Regulations and develop solutions that support the QIPP agenda.

1. Provide advice on what constitutes best practice with respect to the procurement of homecare medicines services including:
 - a) Financial governance
 - b) Clinical governance
 - c) Operational efficiency
2. Provide advice on what opportunities there are for collaboration across the NHS on homecare medicines procurement.
3. Develop guidance for the NHS on when homecare medicines would be an appropriate model of care and, specifically, where it is not.
4. Identify, with support from the wider clinical community, the opportunities to expand and develop the use of homecare medicines services.
5. Provide advice on the actions required to improve the commercial performance of the homecare medicines market (to achieve better value for money, ensure there is competition); this may include suggestions for policy change.
6. Provide advice on the precautions necessary to manage the risk of company failure as commercial performance is challenged.

7. Provide guidance on how the NHS can ensure appropriate collection, collation, dissemination and analysis of information on procurement of homecare medicines (required for PPRS, strategic and operational management).
8. Provide advice on what future work, beyond medicines, may be helpful in developing homecare services for the NHS.

Membership of Steering Group

Mark Hackett, NHS Trust Chief Executive (chair)

Dr Keith Ridge, Chief Pharmacist

Andy Alldred, NPSG chair

Chris Theaker, General Manager, Commercial Medicines Unit

CMU Attendees:

Howard Stokoe

Nickie O'Neill

Liz Payne

Membership of Working Group

NHS Trust Chief Executive (chair)

CMU representatives

NPSG chair

NHMC Chair

Procurement Pharmacist

Clinician

DH Community Pharmacy

Director of Financial management

Senior clinical hospital pharmacy lead

GP Commissioner

SHA Lead

The group will be supported by the QIPP medicines use and procurement work stream wider reference group through a specific sub-group.

Chris Theaker

November 2010

Appendix 1 to Homecare Medicine Review Group: Terms of Reference

Organisation of NHS contracting for pharmaceuticals and national roles of groups and organisations

The NHS (secondary care) contracts for the supply of its medicines in well established and recognised ways. Within their SHA boundaries NHS trusts aggregate their business. The Commercial Medicines Unit then competitively tenders this business on their behalf and awards and manages the resulting contracts.

This enables the NHS to maximise its leverage for generic medicines whilst managing risks to supply and taking into account quality issues. This level of contracting is also considered optimal for branded medicines where it is seen as being the highest collaborative level that the NHS can work at to influence prescribing decisions on a collective basis whilst also maintaining appropriate relationships with primary care and commissioners.

Commercial Medicines Unit

Formally part of the NHS Purchasing and Supply Agency (PASA), CMU is now part of the DH. In very simple terms; CMU contracts on behalf of the NHS for the supply of medicines (as explained above), and also on behalf of the DH where procurements are associated with policy e.g. national immunisation programmes.

A number of Groups support CMU in its role. These include:

CMU Non Executive Board

This Board brings together, at DH level, a small group of NHS and DH stakeholders to review the CMU work programme and to review the interplay between policy and operational NHS management in what is obviously a fast changing healthcare environment.

The National Pharmaceutical Supply Group (NPSG)

Brings together, at National level, NHS Trust Chief Pharmacists (one from within each NHS SHA boundary) to discuss collaborative approaches towards medicines procurement and to provide advice to CMU on the development and maintenance of its business plan.

National Homecare Medicines Committee (NHMC)

A national committee of NHS and industry representatives, that reports to NPSG. The Committee's terms of reference include the development and circulation of best practice focussing on the NHS adherence to good clinical practice and governance.

Support for the Supply Review group

Although it may have to commission specific pieces of work much information will be available to the steering committee from the start. This information will include, for example, the outputs from the NHMC, national market analyses based on nationally electronically collected hospital procurement data (Pharmex) and FP10 (HP10) analyses (PACT), and a DH sponsored exercise to evaluate the market.

November 2010

Appendix B

Homecare Medicines Delivery and Services Supply Review

Steering Group members

Mark Hackett	Chair
Andy Alldred	NPSG Chair
Keith Ridge	DH Principal Pharmacist
Chris Theaker	General Manager, CMU
Howard Stokoe	CMU
Liz Payne	CMU
Nickie O'Neill	CMU

Homecare Medicines Delivery and Services Supply Review

Working Group members

Baljit Ahitan	Lead Pharmacist – Respiratory Directorate (Birmingham Heartlands Hospital)
Diana Bilton	Consultant Physician – Royal Brompton Hospital
Helen Clarke	Chief Pharmacist – Oncology
David Cousins	National Patient Safety Agency
Phil Deady	NHS Pharmacist
Susan Grieve	Principal Pharmacist – Department of Health
Kim Gay	Director of Financial management
Kate Gadsby	Nurse specialist in Rheumatology
Helen Howe	Chief Pharmacist, Cambridge University Hospital
Allan Karr	National Homecare Medicines Committee – Chair
Jonathan Mason	National Clinical Director for Primary Care and Community Pharmacy
Beverley Matthews	Director NHS Kidney Care
Andrew Morgan	SHA Lead
Jo Osmond	Cystic Fibrosis Director – Trust of Clinical Care
Paul Wilson	Lead Nurse Renal Anaemia

Appendix C

To: Regional General Managers
District General Managers
FHSAs General Managers
NHS Trust Chief Executives
GP Fundholders

Copy: Regional GPFH Leads
Regional Purchasing Coordinators
Regional Prescribing Advisers

NHS
Executive

Headquarters

Department of
Health
Quarry House
Quarry Hill
Leeds LS2 7UE

Tel 0532 545000

EL(95)5
17 January 1995

Dear Colleague,

Purchasing high-tech health care for patients at home

Summary

1. DHAs, working with FHSAs, General Practitioners and hospital and community Trusts, should make provision through their contracts by 1 April 1995 to support patients at home whose treatments include the delivery of drugs together with other products and equipment needed to administer them, typically provided as packages of care. The prescribing of these services by GPs on FP10 prescription forms will cease from this date. The essential task for the short term is to ensure continuity of supply to existing patients.

The services: current position

2. People with renal failure or cancer or cystic fibrosis or who are HIV positive or with other conditions may be supported at home following hospital treatment. Some of these patients may need continuous ambulatory peritoneal dialysis (CAPD) or intravenous formulations that may require special compounding and complex administration techniques in the home (including parenteral nutrition and some chemotherapy drugs and antibiotics). The products needed by patients are provided as part of packages of care which include the delivery to the home of everything required to enable them to use the CAPD or intravenous treatment most effectively, including pumps and other equipment for administration and refrigerators for storage. They also include the provision of training for patients and their carers in administering the fluids and infusions and, often, of continuous cover in case of emergency.

3. The treatment of patients at home with many of these conditions is usually proposed by a hospital consultant. However, GPs retain a responsibility for the care of patients at home and often play a role in the clinical management of these conditions through agreed shared care arrangements. The changes with which this guidance is concerned should not have any impact on the important clinical cooperation between consultants and GPs or on the care that patients receive. They are rather concerned with putting the financing of the services onto a consistent and sensible basis. It remains good clinical practice to confirm a proposed treatment with a patient's GP.

4. The main categories of patients likely to be affected, with indications of the sort of drugs and other products being supplied to them, are shown in Annex B. It will be essential for

health authorities to discuss this with their clinical and pharmaceutical advisers in order to clarify what the services are and what drugs and products are involved. We will be providing FHSAs with prescribing data for the main drugs currently being prescribed for patients receiving these treatments.

The changes

5. Ministers have decided that providing these packages of care through GP prescribing, as distinct from the routine prescribing of drugs and other products, is inappropriate. The Department has been discussing other options for providing the services with colleagues in the NHS and has decided that funding will in future be through contracts. This will enable the services to be properly specified and to reflect the fact that they involve elements of hospital, community and primary care. The changes depend on a re-allocation of resources as described below. We recognise that there is a lot of work now to be done locally. We also accept that the main benefits of the changes will take some time to realise, including obtaining better value for money by encouraging competition between a larger number of potential suppliers.

6. By 1 April 1995 DHAs will need to have made provision, through their contracts with hospital or community Trusts or directly with commercial suppliers, to support patients currently being supplied at home with packages of care which include the delivery of drugs or CAPD fluids and other items. The priority will be to ensure complete continuity of supply to these existing patients. Where necessary this might be done by contracting with the supplier currently providing services to a patient until longer term arrangements can be made. For 1995/96 only, DHAs should contract for these services on behalf of all their resident population. From 1996/97 DHAs and GP Fundholders (where the service is within the fundholding scheme) will need to have a strategy for purchasing these services. DHAs will also need to have in place a mechanism which involves agreeing with GPs and providers how to respond to new patients who may require these services or future similar services at home.

7. From 1 April 1995 the provision of these services through the FP10 route will no longer be permissible. It will not be possible for GPs to prescribe on FP10 prescription forms any items or services used in connection with the administration of drugs at home if those items or services are neither drugs nor appliances listed in Part IX of the Drug Tariff. Neither will prescriptions on form FP10 for the drug or fluid itself be regarded as an order for the necessary support items or services. After 1 April 1995 the PPA will return to FHSAs any prescription which appears to order items or services which are not compatible with the provisions of the Drug Tariff. GPs' ability to prescribe drugs and the dressings and appliances listed in Part IX of the Drug Tariff is unaffected.

Funding

8. The present position is that these services are funded through the hospital Trust where the patient's treatment was initiated, by a community Trust, or by the patient's GP signing a prescription. Funding through hospital or community Trusts involves arranging the provision of the service, including the supply of products, to the patient, often through a commercial company. Where services are funded through a community Trust, the products are supplied by a hospital or by a GP signing a prescription. Community Trusts may also currently provide some of the service elements of the care through medical loan arrangements and Hospital at Home Initiatives. Where the funding is initiated by a GP signing a prescription the patient is again often supplied by a commercial company which handles all aspects of the service and processes the prescription as a community pharmacy.

9. Because the current pattern of funding for these services varies the task of making the changes will be different depending on whether these services are currently being funded through contracts with hospital or community Trusts or through GP prescribing. The NHS Executive has identified what is currently being spent on these packages of care in each FHSAs through GP prescribing and appropriate amounts of these resources will be made available to purchasers as recurrent additions to 1995/96 revenue allocations to enable the changes to be made. That is, the funding reflected in GP prescribing will be transferred from the FHS drug budget to the hospital and community health service budget from 1 April 1995. It will be for FHSAs to adjust downwards GP Fundholders' drug budget allocations and GP target budgets for prescribing to reflect the change that is being made.

10. The additional resources are being allocated to RHAs on the basis of what is currently being spent through GP prescribing on these services within FHSAs. Regions will be asked to distribute these to DHAs taking account of any differences between FHSAs and DHA populations. Regions will also need to take account of the fact that the treatment of some HIV patients is through open access clinics outside their Districts of residence. These resources should be sufficient to enable DHAs to meet the additional costs to the HGHS. For 1995/96 only DHAs should contract on behalf of all their resident population (including patients of fundholding practices) for the provision of suitable packages of care either directly with commercial suppliers or with provider units. From 1996/97 the resources will be available to DHAs and GP Fundholders, (where the service is within the fundholding scheme), as a recurrent addition to allocations to purchase these services.

The role of health authorities

11. Districts and FHSAs should work with GPs and Trusts to identify the patients for whom new arrangements need to be made to ensure continuity of service provision from 1 April 1995. For patients where the packages of care are currently provided on GP prescription, Districts need to determine, with the agreement of GPs, how the support will be continued in future and whether this will be within contracts with Trusts or directly with an NHS or commercial supplier able to provide the package of care. In time this will involve agreeing a detailed quality specification and ensuring that the arrangements provide the best value for money. The potential range of suppliers might include commercial suppliers and also some hospital pharmacy departments and some community pharmacists, either alone or in concert with one another or with a community Trust.

12. Districts and FHSAs should ensure that satisfactory arrangements have been made for patients in their locality. They should also communicate details of these arrangements to GPs so that the latter can explain these to the patients who are affected. DHAs should develop a comprehensive strategy for providing these services by 1 April 1996.

13. FHSAs must be clear about what action to take if an FP10 for one of these services is presented after 1 April 1995. That is, they should advise the GP that this route is no longer open and ensure that steps are taken to alert the patient's District which should have made arrangements for the provision of the service.

The role of GPs and GP Fundholders

14. The main tasks for GPs in helping to put these changes into practice are listed in Annex A. A separate PPN is being sent to GPs and community pharmacists drawing the key points to their attention.

15. The central task for GP Fundholders, as for all GPs, will be to collaborate closely with DHAs and FHSAs to identify patients currently receiving these services and to ensure that they continue to receive them from 1 April 1995. GP Fundholders will also need to be in a position to purchase the services, where they are within the scope of the fundholding scheme, from April 1996.

NHS Trusts

16. Trusts must ensure that their staff, including consultants and other clinicians, GPs and patients understand how these services are to be delivered and funded in future. The option of persuading GPs to sign prescriptions for the services will not exist, but the need to discuss and agree with GPs the initiation of such treatment will remain, as will the need to agree a statement of what is required.

Conclusion

17. The immediate task for 1 April 1995 is to ensure that the patients affected by the changes are identified in advance and that arrangements are in place to see that they continue to receive the services they need. DHAs and FHSAs will need to work closely with GPs and hospital and community Trusts to do this. They also need to develop a longer term strategy for the provision of these services from 1996/97 onwards.

18. If you have any questions about this letter please contact Paul Mason, Room 609 Richmond House, 79 Whitehall, London SW1A 2NS, telephone 0171-210-5291.

Yours sincerely,



Alasdair Liddle
Director of Planning and Performance Management
NHS Executive

This letter will be cancelled on 1 June 1996

*EL(95)5 Annex A****High-tech home healthcare for patients at home******Summary of action****DHAs:*

- identify patients being supported at home working with FHSAs, GPs and Trusts;
- make provision for the support of patients at home and develop a comprehensive strategy for doing this by 1 April 1996;
- ensure that arrangements have been made for existing patients currently receiving these services via FP10;
- inform and reassure GHCs, local patient and voluntary groups about the changes.

FHSAs:

- agree changes to prescribing allocations with GP practices (in the context of budget-setting for 1995-96 budgets) to take account of the change in funding route;
- work with DHAs, GPs and Trusts to identify patients being supported at home on GP prescription;
- work with DHAs to ensure that arrangements have been made for patients currently receiving these services via FP10;
- notify GPs in good time about the new arrangements for existing patients.

General Practitioners:

- provide information on request to FHSAs and DHAs about the numbers of the DHA's residents currently receiving one of these care packages on GP prescription and about the hospital which initiated the care;
- Cease prescribing of such services by 1 April 1995: ensure that affected patients understand how they will receive these services after 1 April 1995;
- *GP Fundholders* should be in a position to purchase these services, where they are within the scope of the fundholding scheme, from 1 April 1996.

NHS Trusts:

- ensure that all staff, GPs and patients understand how these services will be provided in future;
- make the arrangements for the support of the patients at home when this has been agreed with purchasers.

EL(95)5 Annex B

High-tech home healthcare for patients at home

The following are the main groups of patients who are currently receiving packages of care at home via GP prescription. This list will help in identifying existing patients. However, there may well be other types of patients in smaller numbers receiving other treatments as part of such care packages on GP prescription.

- Patients with renal failure receiving continuous ambulatory peritoneal dialysis;
- Cystic fibrosis patients receiving intravenous or nebulised antibiotics;
- Cancer patients receiving intravenous chemotherapy agents;
- HIV patients receiving intravenous or nebulised anti-infectives;
- Patients receiving total parenteral nutrition or various types of specialised enteral feed;
- Thalassaemics receiving desferrioxamine;
- Patients receiving continuous anticoagulant treatment.

Appendix E

Contracting Models

Potential positive indicators	Contracting model	Potential negative indicators
<ul style="list-style-type: none"> • Potential price reductions • Assist with any tariff setting or PBR • Nationally agreed specification in line with NHMC • Purchasing power — economies of scale • Market management and overview • Asses risk in the market place • Transparency • Simplifying purchasing process 'once' only • OJEU compliant • CMU procurement and contract knowledge 	National framework	<ul style="list-style-type: none"> • Stifle Service development • Decrease supplier base, depending on awarding criteria • COMMITMENT AND 'BUY IN' BY THE NHS and Supplier base • Reduction of 'added benefits' • Loss of flexibility to account for local needs. • SME's may only want to compete on a local/geographic basis • Could lead to a monopoly supplier situation if not managed
<ul style="list-style-type: none"> • Ability to market manage • Agreed specifications • Compliant and auditable • Benchmarking • Attractive to supplier base • Advantageous pricing • Transparency • Service to fit customer needs • OJEU compliant • Generate completion in the market 	Consortium/Regional	<ul style="list-style-type: none"> • Commitment • Funding and administration of the service across a number of sites • Ability to market manage is only successful if information is shared and all regions contract • Resource to manage and facilitate the commitment and procurement process
<ul style="list-style-type: none"> • Local procurement closer and understands trust strategies and wider local picture • Benefit to SME's • Commitment locally 	Hub	<ul style="list-style-type: none"> • Possibly no economies of scale • Lack of local product knowledge across all therapy areas leading to errors • Lack of specialist dedicated procurement knowledge • Looking after own gains not the whole health economy
<ul style="list-style-type: none"> • Control of individual trust needs • Geographical advantage for supplier base, support local SME's 	Local	<ul style="list-style-type: none"> • Lack of transparency • Inability to market manage if sharing of information is not present • Short term gains due to inability to have a market overview • Potential lack of visibility to ensure value for money is achieved • Legal compliance — open to supplier abuse

Examples of differing contracting levels and working models

Contracting Model	Homecare Market	Comment
National	Clotting factors	<ul style="list-style-type: none"> • Framework in place facilitated and managed by CMU. • 'Once only' approach undertaken to support the NHS • Standard NHMC guidance adopted to ensure best practice model applied • Monitor and manage supplier base • Opportunity for new entrants to bid and tender for the services • National framework adopted to support the nationally lead medicines framework
Regional/Consortium	Renal dialysis	<ul style="list-style-type: none"> • Evidence obtained from facilitation by PASA up to 2008. • Dedicated homecare co-ordinator • Market management • Stakeholder buy in and commitment sort due to direct liaison with all parties • Main focus of procurement staff purely on this market therefore full knowledge and centre of expertise • Knowledge base has the advantage to support and identify any risk in the supply chain and adopt processes to mitigate those risks • Regional frameworks established however, the market was nationally managed by a team of procurement professionally. Clinicians still had the choice of service provider due to the collaborative working of all renal units to eliminate the 'cherry picking' approach by the supplier. • Evidence shows that when this level of contracting was handed back to the NHS to facilitate each of their own consortiums and the facilitation was removed at a national level the NHS did not continue to share, no national lead to facilitate this sharing and market manage resulting in a fragmented service open to supplier control not NHS. • National overview is key and required.
Regional	HIV — Pan London	<ul style="list-style-type: none"> • Currently facilitated and managed by CMU • Regional framework however 60% of the HIV patients fall into the region • Elimination of trust duplication 'once only' homecare tendering expertise not available locally • If no regional framework undertaken their would be a loss of strategic market management • Risk of shortages as a result of less competition • Prices are less competitive and transparency is lost • Framework compliance is high due to local involvement and commitment to the prices and awards • Non commitment could result in reduction in savings as volumes are fragmented

Regional	Main oral out-patients medicines and therapy specific	<ul style="list-style-type: none"> • Undertaken by Leeds Teaching Hospital • Homecare is managed by a dedicated homecare team • Differing tendering is applied relating to the High-Tech and Low-Tech models. • Therapy specific contracting is also undertaken
Hub	All Homecare therapies	<ul style="list-style-type: none"> • One hub has taken the option to tender for 'all' homecare services with all homecare providers • Another has taken the same approach however, undertakes mini competitions against specific therapy areas. • Limited evidence to show if this is fully committed too by the NHS or supplier base.
Local		No evidence of good local practice provided. Concern that EU Procurement regulations may not be adhered to, or that the agreed homecare specifications utilised.

Appendix G

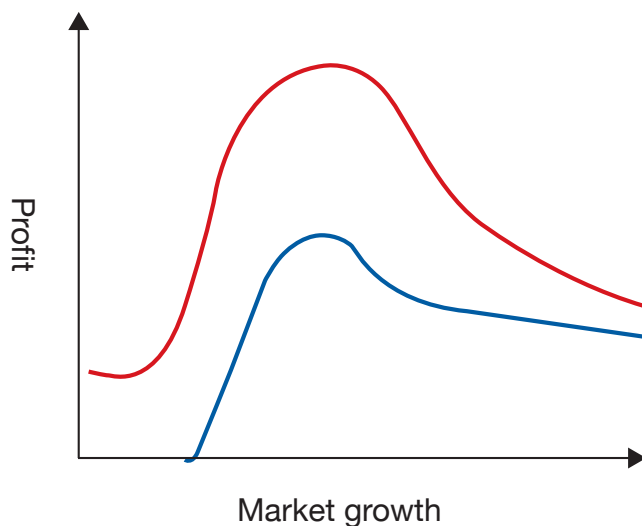
Monopolistic behaviour

A monopolistic market can be defined as a market with many providers selling similar but not identical products or services. Within the market there is a dominant provider which has customer loyalty. In a monopolistic market, advertising, sales and marketing are important.

The homecare market can be viewed as a 'monopolistic' market as there is a clear dominant provider, whilst there are multiple providers, with new entrants joining the market. The service each provider offers is different, but similar.

The risk involved in a monopolistic market is it can turn into a monopoly if the customer is never willing to change provider, and as such brings with it all the risks associated with a monopoly market. The NHS also has to take into account any potential patient negative effects by changing providers, and due to this some customers are not prepared to make the change for little or no cost saving.

A NHS core homecare specification document has been produced to help the NHS and providers see a minimum requirement for the service, and by all customers and providers working to the same specification, a level playing field can be produced and the customer and provider can have more confidence when entering agreements that a symbiotic relationship can be created.



Monopolistic Provider – As the market grows and profits increase, the market becomes tempting for new entrants

New entrants enter, and have increased cost in marketing or sell at lower cost to make them attractive compared to the monopolistic provider

Appendix I

Case Study: the commercial failure of a homecare provider

A homecare provider within the South of England was severely affected by the credit crunch during 2009, in particular the withdrawal of financial support from their main bankers. As a result the homecare provider sought to restructure their business and provide a solution for the NHS and the drug manufacturer to ensure payment of product, to support manufacturer and continuation of supply to support the NHS and their patients. The process aimed to give confidence that all future invoices for product supplied by the homecare provider would be paid.

In order to protect the interest of the manufacturers a trust fund account was set up to safeguard and protect their interests.

The local specialised commissioning group took on the responsibility of providing a guarantee to the suppliers should the scenario have arisen that there was insufficient funds in the trustee bank account to pay the suppliers invoices.

The process which was undertaken was as follows:

- Homecare provider received the medication from the manufacturer at list price or contract price (including VAT) on standard terms.
- Homecare provider dispensed and delivered the products according to the prescriptions received from NHS trusts for their patients on a daily basis. The homecare provider charged the NHS trust at the agreed NHS contract price (excluding VAT) plus the agreed service fees.
- Homecare provider generated a singled invoice per patient per delivery accompanied by the signed proof of delivery and sent it to the respective NHS trust on a daily basis.
- Homecare provider invoices required payment from the NHS trust on strictly 28 days from date of invoice. The homecare provider initiated an internal chase payment process.
- Invoices were paid directly by the NHS trusts into the new 'trustee Account' the homecare provider had no access or control over the account and it was operated by an independent administrators of the account.
- Additional procedures were provided to ensure confidence and no leakage of cash from the trustee account. These tests covered monthly account statement reconciliations, monthly supplier reconciliations, including rebate reports and monthly NHS trust debtor reconciliations.

It should not be under estimated the good will and support given to the homecare provider by the local specialised commissioning group and NHS trusts to work together towards a common goal of continued patient care and solutions to ensure the homecare provider continued to trade and offer a service.

Sample financial analysis**Key Financial Ratios**

Profitability: profit the organisation is making which gives an indication of market movements and positioning

EBITDA Margin = Earnings before Interest Tax Depreciation Amortization / Total Revenue

Net Profit Margin = Profit or Loss for period / Total Revenue

Liquidity and Efficiency: Ability to pay of debts and amount owed

Current Ratio: Current Assets / Current Liabilities

Liquidity Ratio: (Current Assets – Stock) / Current Liabilities

Capitalisation and Solvency: Capital and funding

Gearing Ratio: (Total Long Term + short term Loans) / Total Equity

Interest Cover Ratio: Operating Profit or Loss / Interest paid

Tangible Net Worth: Total Equity – Intangible Assets

Appendices

Profitability	Net sales ('000 £)	EBITDA Margin	Net Profit Margin
Supplier 1	675,566	2.87%	-6.52%
Supplier 2	203,829	1.80%	1.26%
Supplier 3	59,153	0.25%	0.12%
Supplier 4	16,497	-11.59%	-9.44%
Supplier 5	19,147	10.76%	7.77%
Supplier 6	16,801	8.37%	6.12%
Benchmark	N/A	6.91%	3.87%

Liquidity and efficiency	Current ratio	Liquidity ratio
Supplier 1	1.32	1.11
Supplier 2	1.12	0.97
Supplier 3	0.98	0.87
Supplier 4	1.84	1.57
Supplier 5	0.96	0.95
Supplier 6	1.26	1.00
Benchmark	1.11	0.84

Capitalisation and solvency	Gearing ratio	Interest covered ratio	TNW ('000 £)
Supplier 1	309.00	-0.15	-125.767
Supplier 2	156.00	7.55	16.110
Supplier 3	0.00	19.75	-13
Supplier 4	-215.00	-14.5	-2.555
Supplier 5	117.00	0	2,002
Supplier 6	0.00	0	1,221
Benchmark	151.16	4.17	N/A

Appendix J

Dr Keith Ridge letter 26th February 2010


 Skipton House
 80 London Road
 London SE1 8LH
 Tel: 020 7972 2000
 Direct Line: 020 7972 2833
 E-mail: keith.ridge@dh.gov.uk

Gateway reference: 13761

NHS Hospital Chief Pharmacists in England

26th February 2010

Dear Colleague

EXPORTING MEDICINES FOR PROFIT

On the 14th July 2009, I wrote to you expressing my serious concern about reports that some hospitals were considering exporting, or selling for export, medicines for the purpose of profit.

In the letter I pointed out this was unacceptable. I remain of that view as export of medicines could threaten the medicines supply chain and, in turn, threaten patient care. This is contrary to professional behaviour. Indeed the Royal Pharmaceutical Society of Great Britain issued a law and ethics bulletin in July 2009 which stated:

"The Code of Ethics requires pharmacists to make the care of patients their first concern. Pharmacists are advised that the export of medicines for commercial or financial gains could be considered a breach of Principle 2 of the Code of Ethics."¹

The NHS Chief Executive, David Nicholson, has now written² to NHS Trust Chief Executives to highlight that engaging in the trade of medicines jeopardises both patient care and NHS contracts for medicines, and asks Chief Executives to ensure that their organisation is neither engaged in, nor planning to engage in, such activities. Monitor will be writing to NHS Foundation Trusts in similar terms.

I fully support this action and if necessary, I will ensure that any registered NHS hospital pharmacist involved in exporting medicines for profit, to the detriment of patients, is called upon to justify his or her actions. I am asking through this letter that SHA pharmacy leads and members of the National Pharmaceutical Supply Group provide me with the full details of any NHS hospital they know to be exporting medicines for profit.

I should point out that I am fully aware that the vast majority of hospital pharmacists would not remotely contemplate exporting medicines for profit and always focus their efforts entirely on providing high quality patient care.

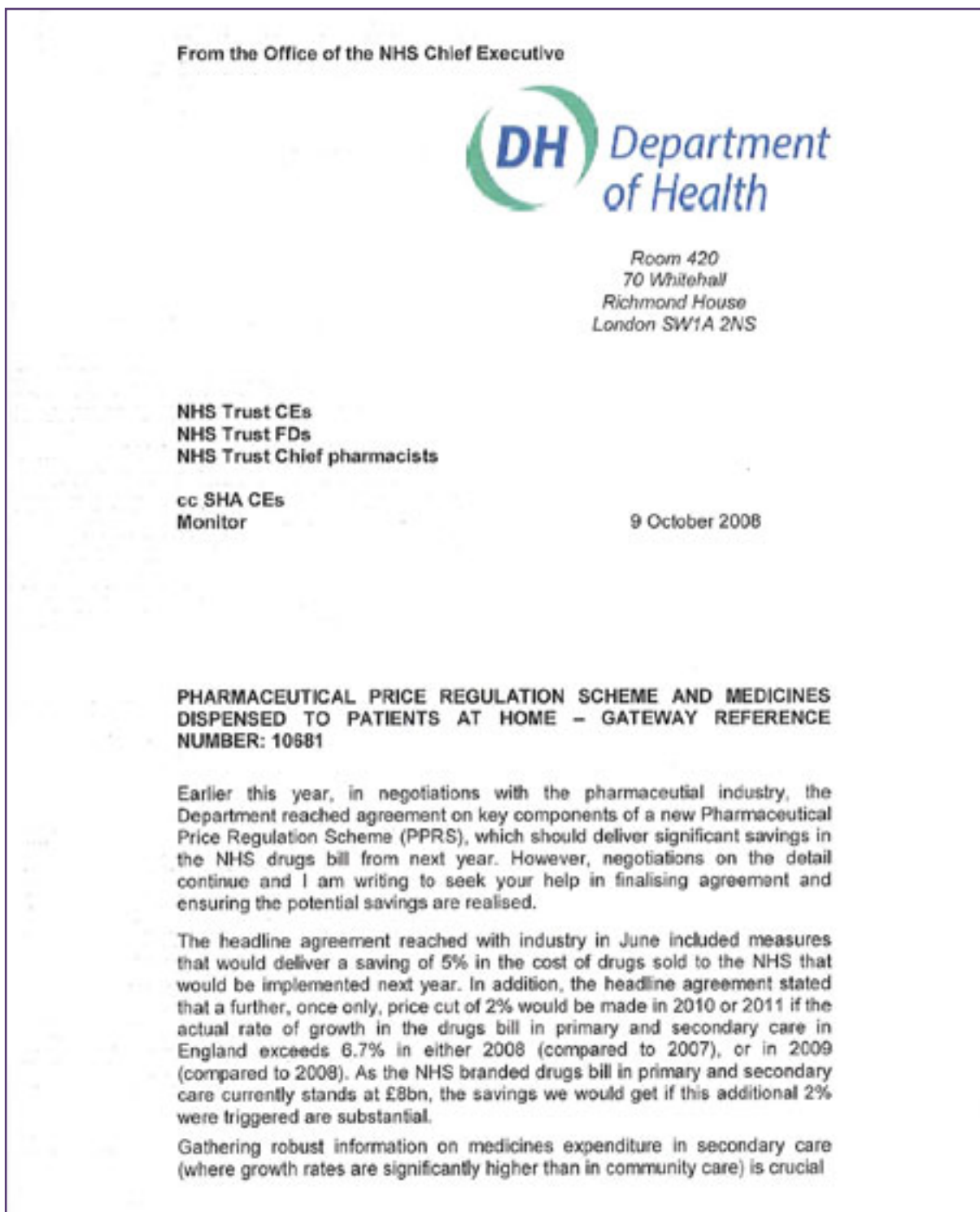
Yours sincerely



Dr Keith Ridge
 Chief Pharmaceutical Officer

Appendix K

Sir David Nicholson letter 9th October 2010



From the Office of the NHS Chief Executive



to this exercise. To date, we have had good support from hospital pharmacists in gathering data on secondary care through NHS PASA and a system known as Pharmex, which collects data from the 95% of NHS Trust pharmacy systems that are able to provide it.

However, there are gaps in the information available through Pharmex – most notably information on medicines dispensed at home where purchasing sometimes bypasses pharmacy information systems. Many NHS Trusts have developed comprehensive pharmacy information systems including homecare data, but coverage is patchy across the country.

NHS PASA are writing to hospital pharmacies looking for any further data on expenditure on medicines not entered into hospital pharmacy systems, most likely those that are dispensed in a home setting. They will not be looking for you to duplicate information already available through Pharmex or other systems. The aim is to identify whether there is additional information trusts may have which would support us in developing a comprehensive information set on the total drugs bill in 2007, 2008 and 2009.

I am writing to seek your support in identifying any relevant information you may be able to provide NHS PASA when they contact your Trust. This will be crucial in determining whether or not an additional 2% price cut is triggered for the NHS as a whole in 2010 or 2011.

If you require any further information on this issue, please contact Howard Stokoe (howard.stokoe@pasa.nhs.uk) or Chris Theaker (chris.theaker@pasa.nhs.uk) or ring NHS PASA on 0118 980 8850.

Monitor are writing in the same terms to NHS Foundation Trusts.

A handwritten signature in black ink, appearing to read 'D Nicholson', is positioned above the printed name and title.



DAVID NICHOLSON
NHS Chief Executive

Appendix L

Homecare Medicines Review Group The Leeds model

- Background to LTH and homecare medicines management
- The Homecare Medicines Review Group's Terms of Reference and LTH practice
 - Financial governance (1)
 - Clinical governance (1)
 - Operational efficiency (1)
 - Collaboration on homecare medicines procurement (2)
 - Homecare medicines and data management (7)

(figures in brackets refer to the Terms of Reference document)

Medicines Management & Pharmacy Services  The Leeds Teaching Hospitals  NHS Trust

Leeds Teaching Hospitals NHS Trust



- Over 3,000 inpatient beds
- 5 hospital sites across the city
- Patients from Leeds, Yorkshire & Humber and further afield
- Many tertiary specialities
- Good working relationship with commissioners on medicines

Medicines Management & Pharmacy Services  The Leeds Teaching Hospitals  NHS Trust

Leeds Teaching Hospitals NHS Trust – Homecare medicines facts and figures



- First homecare patient in 1981 (parenteral nutrition)
- 3,500 patients on homecare medicines services (2009/10)
- ~30 different homecare therapies
- Total spend on homecare medicines and services £30M (2009/10)
- Total pharmacy homecare administration costs estimated at £50 per patient per year

Medicines Management & Pharmacy Services



The Leeds Teaching Hospitals NHS Trust

1. Financial governance

There are different and specific areas of homecare medicines management that relate to financial governance:

- a) Procurement
- b) Audit requirements relating to orders, invoices and payment
- c) Reporting and monitoring medicines spend

Medicines Management & Pharmacy Services



The Leeds Teaching Hospitals NHS Trust

1. Financial governance: (a) Procurement

- There are 2 types of homecare medicines service:
 - NHS lead
 - Pharmaceutical industry lead
- LTH tenders for all NHS homecare medicines services contracts
- LTH tenders for the medicines that are provided through pharmaceutical industry contracted homecare services (the contract for the homecare service is between the pharma company and the homecare company)
- LTH is a member of the Yorkshire & Humber NHS Pharmaceuticals Purchasing Consortia – our strategy is to move NHS homecare medicines service contracting from Trust to Consortia level
- EU regulations are complied where applicable
- Trust Standing Financial Orders and Instructions are complied with

Medicines Management & Pharmacy Services



The Leeds Teaching Hospitals **NHS**
NHS Trust

1. Financial governance: (b) Audit requirements relating to orders, invoices and payment



Medicines Management & Pharmacy Services



The Leeds Teaching Hospitals **NHS**
NHS Trust

1. Financial governance: (c) Reporting and monitoring medicines spend

- All (bar one) homecare medicines are managed using the Pharmacy IT system (JAC)
- Structures have been put in place that have developed a strong working relationship between Medicines Management & Pharmacy Services (MMPS) and Finance
- There is a Medicines Finance Operational Group that meets bi-monthly, chaired by the Clinical Director MMPS or the Director of Financial Management
- Spend on homecare medicines services is reported monthly and monitored on an on-going basis
- An annual report on homecare medicines management is produced by the pharmacy procurement team and tabled at the above meeting
- Directorate accountants work closely with pharmacists working in clinical specialities to investigate unusual increases or decreases in spend on an on-going basis

Medicines Management & Pharmacy Services



The Leeds Teaching Hospitals **NHS**
NHS Trust

2. Clinical governance

- "Out of site is NOT out of mind"
- Policies and Procedures
- Performance management frameworks
- Quality Assurance of the homecare suppliers
- Quality Assurance of unlicensed homecare medicines (eg. HPN)
- Patient surveys
- Risk assessment of newly proposed homecare schemes
- Examples include:
 - Incident reporting
 - Complaints management
 - "Being Open"
 - Clinical policies, procedures and guidelines (eg. medical device maintenance, care of central venous catheters, extravasation of chemotherapy)
 - National Patient Safety Alerts

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3. Operational efficiency

- Management of homecare medicines is the responsibility of the Pharmacy Procurement Manager
- Leeds has developed expertise in using the MMPS IT system (JAC) to help manage homecare medicines and services
- As homecare medicines services have grown, there has been resource put in place to help manage the services (eg. homecare invoice administrators, Specialist Technician in Homecare Medicines Management)
- Leeds MMPS homecare administration costs have been calculated at £50 per homecare patient per annum (08/09)
- There is centralisation of homecare medicines invoice clearance at one hospital site (Moor House, home of the procurement team)
- The procurement team use their expertise to design operational efficiency into the service specifications when tendering for homecare medicines services (eg. putting the onus on the homecare supplier to submit spend and patient data, follow incident reporting procedures, etc.)

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4. Collaboration on homecare medicines procurement

- The Yorkshire & Humber NHS Pharmaceuticals Purchasing Consortia has a strategy to move from Trust to Consortia level homecare medicines service contracts
- Collaboration is currently with the 15 acute Trusts and one primary care provider organisation that make up the membership of the Consortia
- As with all medicines procurements, multidisciplinary clinical project groups support the tender process from idea to implementation and beyond
- Many homecare service contracts have already been tendered at Consortia level (eg. EPO, methotrexate, outpatient medicines)
- Many are planned to be tendered at Consortia level (eg. IV antibiotics/antifungals, parenteral nutrition)
- Leeds and the Consortia aim to support national homecare medicines procurement through membership of the National Homecare Medicines Committee and close collaboration with NHS CMU

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5. Homecare medicines and data management

- Key to success is use of the Pharmacy IT system to manage homecare medicines and services
- All but 1 of the 30+ homecare medicine services at Leeds are managed through the MMPS IT system (JAC)
- This leads to good data being readily available for the majority of homecare medicines services – the ability to identify spend in each clinical area and for the Trust as a whole
- There are still some therapies that we haven't yet got complete control of data (eg. HIV medicines homecare – we can see spend but not drug -level detail)



Homecare medicines management issues

- Waste?
- Administrative burden
- Manual prescribing and validation
- Ordering/invoicing not completely electronic
- No agreed sharing of non -tariff savings
- LTH responsibility for quality



Summary – characteristics of the LTH approach to homecare medicines management

- Clinical Director MMPS – leadership, accountability
- Relationships between MMPS and Finance at all levels
- Procurement Manager – leadership, operational implementation, performance management
- Procurement team – resource, expertise, centralisation, efficiencies
- MMPS IT system (JAC) – working around limitations to make it work for our needs
- Visibility of homecare medicines – all aspects, all levels
- Procurement – LTH and Y&H Consortia
- Procurement – EU regulations, Trust SFIs
- Clinical governance – supplier performance management framework and patient surveys
- Prescription/Order/Invoice process – best practice

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Summary: the QIPP agenda and homecare medicines management

<p>Quality</p> <ul style="list-style-type: none"> • Prescribing and validation of homecare medicines prescriptions • Contracting for homecare medicines services • Performance management of homecare suppliers • Incident reporting • Patient involvement 	<p>Innovation</p> <ul style="list-style-type: none"> • Proactive scanning for homecare opportunities • Collaboration across Yorkshire and the Humber
<p>Prevention</p> <ul style="list-style-type: none"> • Hospital admissions • Hospital outpatient attendances • Learning from incident reporting and patient surveys 	<p>Productivity</p> <ul style="list-style-type: none"> • Centralisation of pharmacy homecare administration services • Best practice approach to the homecare patient pathway

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Appendix M

Medicines And clinical services dispensed to patients at home

Commissioning for Quality Assurance Executive Summary

There has been considerable growth in the use of homecare companies to provide medicines to patients direct to their homes. This development has evolved over a relatively short timescale and has meant that order/invoice processing, tendering and formal contracting and monitoring of these services is widely variable. The scale of this activity is of national concern (approximately £800M nationally) and the wide and varied arrangements for order/invoice processing do not support data capture that would allow meaningful comparisons to be made between health economies.

Commissioners require an assurance that such service provision is associated with good governance from both a clinical and financial perspective.

Greater control of this activity can be achieved if all order/invoice processing for use of homecare companies to provide medicines to patients direct to their homes is brought in house into trust pharmacy departments. However this has resource implications for trusts which are difficult to determine and variable according to patients and their treatment needs.

Analysis of provider Trust pharmacy activity associated with use of homecare companies to provide medicines to patients direct to their homes based on work at Leeds Teaching Hospital NHS Trust cost is approximately £50.00 per patient per year this includes key performance indicators and key governance issues relating to contract and performance management. Provider Trusts in the West Midlands analysis represented a cost £27.50 per patient per year but did not include full contract management and governance.

This paper offers support to PCTs when commissioning homecare company provision of medicines to patients at home and identifies key recommendations and issue for consideration of this rapidly growing service and market.

1. Background and Introduction

- 1.1 A medicine homecare service can be described as one that delivers ongoing medicine suppliers and where necessary associated care, initiated by a hospital prescriber, direct to a patients' home with their consent.
- 1.2 The purpose of the service is to improve patient care and choice for their clinical treatments. Patients that are typically on homecare are those with chronic diseases and stable treatment regimens that do not require acute care input.
- 1.3 Currently, most homecare is initiated by Hospital Trusts which normally administer medicines to patients within their own hospital environment. However, on some occasions the supply and administration of medicines is better provided directly to the patient in their own home.

- 1.4 There has been considerable growth in the use of homecare companies to provide medicines and services to patients direct to their homes. Whilst there are many benefits to this (see later) this activity has grown from a relatively small number of patients (a few cystic and home HPN patients) to a large number of patients with a wide range of clinical conditions and needs (HIV, rheumatology, renal, haematology, endocrine disorders, antibiotics, neurology, oncology, osteoporosis etc).
- 1.5 This development has evolved over a relatively short timescale and has meant that order/invoice processing, contracting and monitoring of these services is widely variable. Where hospital pharmacy departments are involved in the process this is further confounded by the variety of pharmacy computer systems used between hospitals.
- 1.6 The scale of this activity is of national concern, the number of patients receiving their medicines via the homecare route is estimated at 120,000 (approximately £800M nationally). These figures are expected to increase substantially as clinical services follow the vision of building on the strength of pharmacy, using their capacity and capability to deliver further improvements in pharmaceutical services over the coming years as part of an overall strategy to ensure safe, effective, fairer and more personalised patient care. ¹
- 1.7 A large number of branded medicines are now also being supplied to patients and the related activity is not captured through existing systems. In respect of this, and to support developments in the Pharmaceutical Price Regulation Scheme (PPRS), the NHS Chief Executive has written to all NHS Trusts and NHS Foundation Trusts (Gateway Ref No 10681) to seek support for the capture of this activity via the Pharmex database or the Prescription Pricing Division's prescription Cost Analysis (PCA) system).
- 1.8 No PbR tariff exists for medicines provided by homecare companies, and commissioners are generally excluded from arrangements for these services where they often feel they are just presented with the associated invoice.
- 1.9 The wide and varied arrangements for order/invoice processing do not support data capture that would allow meaningful comparisons to be made between health economies. Such comparison is valuable as a clinical governance tool and since many products supplied to patients via home care companies are high cost, this is also a financial governance issue.
- 1.10 Region wide contracting will help reduce costs paid to homecare companies but is unable to provide necessary and meaningful benchmarking data to make activity comparisons between health economies.
- 1.11 Many of the above issues can be addressed or supported if all homecare order and invoice processes are brought in house into hospital pharmacy departments.

¹Department of Health, publications – pharmacy in England; building on strengths – delivering the future

- 1.12 Medicines supply via homecare companies often bypasses the normal procurement and distribution structure. The lack of pharmacy involvement in areas of homecare where pharmaceuticals are used is not a tenable position.

2. Benefits of Homecare Service

- 2.1 There are many benefits in using homecare, key among which is that for many patients it would be necessary to make visits to hospital solely to receive periodic treatment or prescriptions. Homecare services avoids this need, thereby also freeing both patient and hospital time. This may also benefit commissioners in terms of PbR tariff patient attendance fee.
- 2.2 Homecare provision is consistent with NHS patient choice agenda.
- 2.3 Where appropriate homecare services can be commissioned with nursing support to ensure seamless delivery of care without creating any burden to community services.
- 2.4 Where patients are receiving a range of home medicines, homecare may offer the opportunity of providing all medications through a single provider.
- 2.5 Provision of medicines direct to patients via homecare is VAT exempt and this saving funds the service provision or reduces costs.
- 2.6 Given that homecare services are for individual patients it should be possible to accrue additional benefit e.g. in tracking of patient activity. This has not proven to be the case and the reasons for this are unclear but believed to lie in the variability of order/invoice arrangements that exist.
- 2.7 Homecare offers the opportunity of providing high quality, cost-effective and accessible care to specific patient groups.

3 Current order/invoice arrangements

- 3.1 Homecare companies currently receive orders via a number of routes
- on a company proforma direct from a clinician without input from pharmacy or other NHS procurement organisation
 - on a company proforma direct from a clinician with an associated order from pharmacy or other NHS procurement organisation
 - via a FP10(HP)
- 3.2 Invoices may be sent from the homecare company direct to:
- the patient's PCT
 - the hospital pharmacy department who verify and pass for payment by the hospital finance department who may then invoice the PCT depending on local contract arrangements
 - the hospital finance department who verify and invoice the PCT

- 3.3 The variety of the above arrangements offers scope for error. Consistency would eliminate this potential.
- 3.4 Current arrangements outside of pharmacy departments do not allow for clinical checks to ensure compliance with NICE, or other local formulary agreements. Such arrangements may also circumvent the requirement to ensure individual patient funding is in place, prior to orders being placed.

4 Commissioner perspective

- 4.1 PCTs need an assurance that:
- Patients for whom they are invoiced are their patients (this may necessitate a Patient/GP identifier)
 - Treatment provided is in accordance with NICE or other locally agreed guidance
 - the goods invoiced for have been received
 - Value for money is being obtained — formal tender and contracting process is undertaken and performance measures introduced
 - The service provided by the appointed contractor is monitored regularly and thoroughly
 - costs incurred are consistent with commissioning policies
 - There is an opportunity for independent patient level audit and benchmarking of activity
 - Usage of high-cost drugs outside of PbR is consistent with other health economies.
- 4.2 Continuation of the current arrangement which doesn't facilitate or allow for robust interrogation and verification of activity is not sustainable.

5 Hospital pharmacy order/invoice processing of all medicines related homecare activity

- 5.1 Transfer of order invoice processing of high tech medicines provision to hospital pharmacy departments is consistent with previous NHS strategy to improve medicines management e.g. EL(95)5
- 5.2 The above issues can be addressed if all homecare activity is managed by the hospital trust responsible for the associated episode of the patient's care. Management of such orders and invoices will need to include:
- The processing of all orders to a homecare company for medicines and associated consumables and ancillary devices to be delivered to a patient's home
 - The passing and processing of invoices from homecare companies for payment by finance departments (N.B. whether this is via the hospital finance department or direct to PCT finance department will be subject to local agreement)
- 5.3 To deliver on the requirements of PCTs and support the PPRS strategy as in the NHS CEO letter above all pharmacy orders for homecare will need to be logged on individual hospital trust pharmacy department computer systems to enable:
- Data capture via Pharmex for purposes of PPRS contracting activity

- Data capture via IMS for purposes of benchmarking of activity

5.4 In addition, it will be necessary for hospital pharmacy departments to maintain a patient database tracking system for each patient's individual activity and requirements to support good patient monitoring and monitoring of homecare provision.

5.5 The above requirements significantly add to hospital pharmacy activity and the processes associated are complex and time consuming (see **Appendix 1**).

6 Hospital pharmacy resource needs to support order/invoice processing and patient monitoring

6.1 These are imprecise (see **Appendix 1**) and are affected by case mix and volume of activity. However, unless all homecare order/invoice activity is managed by hospital pharmacy departments it is difficult to see how the requirements of PCTs and the NHS CEO PPRS strategy can be delivered.

6.2 In addition, it is possible that efficiencies in the processes can be achieved with experience, economies of scale and technological development.

6.3 In the meantime it is necessary for PCTs to have a guide that can be used in local negotiation. Such a guide is incorporated in **Appendix 2**.

7 Recommendations

7.1 PCTs should, through commissioning arrangements, ensure that all order/invoice processes medicines provided by homecare companies are managed via hospital pharmacy departments, and activity data captured on hospital pharmacy computer systems.

7.2 PCTs to commission homecare activity through their local provider trust and, supported by information in this paper, provider trusts to enter into negotiation with commissioners around the level of resource required delivering this activity.

7.3 PCTs should regularly review the requirement for or quantity of this resource need in the light of potential technological or economy of scale efficiency gains, alternative methods of provision or national consensus.

7.4 PCTs should, through commissioning arrangements, specify reports and information needs to provide assurance in respect of clinical, financial and corporate governance.

7.5 PCTs should, through commissioning arrangements, ensure that provider trusts have robust mechanisms for "gate keeping" of medicines procurement through "homecare" providers, in accordance with any specific commissioning and funding policies in place.

8 How do I find out more about homecare services?

- 8.1 Acute and PCT pharmacy leads are usually best placed to advise on local homecare services in the first instance. Alternatively you may also wish to contact your regional procurement specialist pharmacist or Commercial Medicines Unit homecare team:- Details of your regional representative and homecare team can be found on the Commercial Medicines Unit's website www.cmu.nhs.uk

References

1. Department of Health, publications — pharmacy in England; building on strengths — delivering the future

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Appendix 1 to Medicines and Clinical Services dispensed to patients at home

Hospital Pharmacy based order/invoice processing for medicines Provided direct to patients' homes via homecare services

Based on four Trusts in the West Midlands who have experience of placing orders for medicines provided via a homecare company and receiving invoices (plus authorising for payment) the following key steps in the process were identified:

Placing an order

1. Consultant completes the homecare company patient registration form and writes a prescription. Both are sent to the hospital pharmacy department for processing.
2. A pharmacist clinically screens the prescription, confirms that funding is available for each patient's treatment and signs the prescription and patient registration form. These forms are then passed to a pharmacy clerical officer.
3. The Pharmacy clerical officer creates a folder for each individual patient to retain a copy of the completed Homecare Company patient registration form, prescription and pharmacy department specific form for tracking details of orders placed and stock supplied (Generic patient registration form can be found at www.cmu.nhs.uk/homecare/Pages/homecareguidance.aspx).
4. Each patient is separately identified and entered on the pharmacy computerised order system as an "order". N.B. This will vary depending upon the pharmacy computer system software.
5. Each medicine supplied to a patient has to be set up on the pharmacy computer system as a homecare "issue" and include a data set field for all associated components e.g. consumables, delivery, nurse, equipment and training attendance/administration, other co medicines that may be required/used
6. Via the pharmacy computer system, the pharmacy generates a purchase order for the quantity of drug specified on the prescription received (usually three month supply). N.B. For home TPN this is more complex since the prescription details will vary. This necessitates an "open" order to cover goods supplied — see paragraph 2 on the next section titled "Invoice receipt"
7. A copy of the purchase order (with the copy of the prescription and patient registration form as in 3 above) is retained in the patient folder created in 3 above.
8. Originals of the purchase order, prescription and homecare company patient registration form are faxed, and then posted, to the homecare company service provider.

Invoice receipt

1. Invoices are sent to the pharmacy placing the order along with delivery notes (one delivery note for each attendance/delivery to a patient's home) detailing the quantity of goods or the services supplied. Evidence of goods receipt is by either patient, relative or carer signature on the delivery note.
2. Details from the delivery notes are then "received" onto the pharmacy computer system and "issued" (booked out) to a patient or defined cost centre whilst taking care to ensure the "goods" received match the order placed. Where necessary this may be checked, against the pharmacy Patient Medicine Record or other locally maintained database for homecare patients when discrepancies arise. There is a need to ensure an internal pharmacy monitoring system is in place for outstanding orders/deliveries. N.B. For home TPN this is additional complexity since prescription details may vary in month. For each invoicing period (usually one month) delivery notes and invoices forwarded to pharmacy require checking of each individual supply to a patient. The pharmacy generates an order on the computer system for each supply where there is prescription variation.
3. It is important to check at this point that stock received and booked out results on stock "held" as zero. This ensures that deliveries and issues have matched.
4. The invoice received can be reconciled onto the pharmacy computer order system and authorised for payment by the appropriate (hospital or PCT as locally agreed) finance department.

N.B. Local Standing Financial Instructions require that the order/invoice trail is auditable and this normally requires the staff involved in the process to be different at key steps i.e. the person placing the order is different to the person receiving the order who is different to the person passing the order for payment.

Other issues

1. Each homecare company sends a monthly patient activity report to the hospital pharmacy department. This is checked in pharmacy to validate by matching the information against invoices received and individual patient records. When confirmed the report is sent to the appropriate (hospital or PCT as locally agreed) finance department who then check to ensure the appropriate PCT has been invoiced.
2. Patient's condition/disease progression changes necessitating changes in treatment regime, often at short notice.
3. Patients are sometimes admitted as inpatients and on such occasion their homecare provided product may or may not be used and there may or may not have been time to cancel/postpone deliveries. In addition the patient may not be admitted to the hospital that maintains their homecare order and in some instances the drugs that would normally have been provided via homecare are provided via the hospital pharmacy.

N.B. Monthly validation of activity reports from homecare companies is always in arrears of the activity undertaken and not always co-terminus with the orders placed or invoices received.

Appendix 2 to Medicines and Clinical Services dispensed to patients at home

Resource implications of bringing into hospital pharmacy departments all order and invoice processing for medicines and associated services provided via homecare companies

Whilst **Appendix 1** sets out the steps involved and some key issues in relation to order and invoice processing for medicines and associated services provided via a homecare company, quantifying the associated resource need to deliver this is imprecise. This is further confounded by:

- the nature of the patients (complexity of individual monitoring required according to their illness)
- the medicines they receive (complexity of medicines e.g. TPN, HIV, anti TNF alpha)
- provision of associated consumables (syringes, giving sets, refrigerators etc), administration (e.g. patient training, nurse administration)
- patient management/monitoring by homecare nurse) and frequency of service provided (e.g. number of product "drops", number of nurse attendances needed)

To this list could be added hospital pharmacy department issues such as new patient set up, differing computer systems, specialisation, economies of scale etc.

Therefore to determine the resource needs one of the four trusts involved in developing this paper undertook a "time and motion" study of steps in the process for order/invoice processing using a sample size of 200 patients over one month. The results were discussed with other members of the group and agreement reached as follows:

Appendices

Key step	Time (minutes)	Staff group pay band (pay pt)	Annual Cost (based on mid point of 2009/10 scale plus 30%)*
Raise purchase order	116	3 (pt 10)	258
Sign purchase order	21	8a (pt 37)	116
Photocopy/fax/post prescription and order	225	2 (pt 6)	442
Check delivery note and invoice	270	2 (pt 6)	530
Receive goods	73	3 (pt 10)	162
Issue goods	335	2 (pt 6)	658
Reconcile invoice	400	2 (pt 6)	785
Invoice check/authorisation	60	8a (pt 37)	330
Filing paperwork to individual patient folders	540	2 (pt 6)	1,060
Statement check against invoices reconciled	240	5 (pt 21)	745
Collating information for finance departments (end of month data set)	70	5 (pt 21)	217
Problem solving/trouble shooting	135	3 (pt 10)	300
Total			5,510 per 200 patients i.e. approximately £27.50 per patient per year**
N. B. To set up the system for a new patient takes approximately 15 minutes of a band 5 technician as a one off cost per patient.			

*Mid point of the pay scale is used to eliminate variation in scale progression and an on cost of 30% is used to reflect employer on costs, and staff absence/cover etc. It should be noted that use of mid point and on cost figure may vary slightly between hospitals

**It is important to note that the above costs and activities relates solely to order/invoice processing and a number of additional important and necessary functions related to contract management for homecare service provision has not been identified in the above, however, Leeds have worked on these costing and it calculates to approximately £50.00 per patient, when key performance indicators and key governance issues relating to contract management are included. these functions have not yet been taken on board The National Homecare Medicines Committee facilitated and managed by CMU have begun work to identify those functions that need to be fulfilled if homecare contracts are to be properly managed and these are seen as key contracting governance issues, they include:

- Contract negotiation
- Contract tender specification set up (this will necessitate local clinical engagement and clarification/ negotiation regarding their role) *
- Pre-tender meetings with potential suppliers
- Contract adjudication *

- Post contract monitoring and service review meetings with homecare company providers
- QA of service from homecare provider
- Identification of and measurement against key performance indicators for homecare company providers i.e. to monitor performance/accuracy of provider (currently the only check is the invoice reconciled in Pharmacy against delivery note!)*
- Liaison with finance departments
- Finance department costs associated with ledger maintenance for patients and re-charge to individual PCTS
- Provision of patient reports to PCTS
- Patient surveys

***Sample documents can be found at:**

<http://cmu.dh.gov.uk/homecare/> or email liz.payne@cmu.nhs.uk for further information

It is clear that the above components of contracting need to be taken into account and will necessitate local trust involvement. We should look to the National Homecare Medicines Committee for guidance in respect of this. In addition some products may lend themselves to national contracting whilst others may be on an SHA or local basis.

However, work reported from Leeds at a recent National Medicines and Homecare Symposium demonstrated that pharmacy establishment costs associated with homecare company contract management and order/invoice processing was approximately **£50 per patient** (see Pharmaceutical Journal February 28th 2009 p 230).

Appendix N

How do Trusts select which product(s), service and supplier to support their homecare services?

Current NHS Position

There are two types of decisions that trust staff needs to make:

1. Which homecare provider should be used?
2. Which product(s) and service should be subjected to homecare provision?

(1) How are Homecare providers approved?

Homecare providers are often selected based upon the reputation of the homecare supplier or from a limited choice provided by a Pharma company who offers their product homecare service free of charge. Homecare companies historically provide a range of different services which may differ at various times, depending upon the quality and number of staff allocated to the specific service. Pharma companies often select their own preferred homecare provider, which could be based upon a wide variety of factors, particularly cost. It is inherently difficult for a trust then to select a homecare provider based upon their performance. Until this process changes, price seems to be the dominant factor through an appropriate OJEU tendering process or simply to agree to a Pharma company's selection because it is provided at no cost.

In order to provide a homecare service, each homecare provider will need to ensure that they have the various legal and other frameworks in place e.g. MHRA, GPhC, CQC. These core standards are needed before the organisation can operate a homecare service. There are other types of nationally recognised quality standards which can demonstrate high performance and that can be obtained e.g. ISO 9000. Many homecare providers have these additional standards, or are in the process of gaining them.

Also, each homecare provider will have undergone an inspection from a Regional Quality Control and NHS Procurement Pharmacist. Unfortunately resources for extending these audits are currently limited. Plans are beginning to be considered for a homecare provider self-audit process to supplement these arrangements.

There are inherent difficulties in monitoring a company's homecare performance, especially as by definition, the service is not provided on site. A set of KPI's is being developed by the NHMC to try and provide further useful data on provider performance. However, this data is being collected and viewed at local level only. Other methods used, including patient satisfaction surveys, can assist the process may not be robust enough to reveal sufficient detailed information for the purposes of establishing supplier preference. In the future, the development of a process of aggregating KPI data and the use of 'track and trace' systems may provide enhanced analysis and a greater understanding of service performance.

(2) Which products and services should be subjected to homecare services?

The process by which trusts select products and types of homecare service they wish to provide is variable. Decisions are often based upon local interest, knowledge and capability. Development of a homecare service is therefore often seen as being provided in an ad hoc manner, rather than being planned in a strategic fashion.

A list of known products which are being provided by homecare suppliers has been produced by the NHMC based upon local feedback from a small number of users. The list which is not exhaustive, does not describe the type of service in detail or the value of the service in financial or clinical benefit.

There is no national view on how a medicine homecare service should be approved. Local healthcare organisations have different methods of approving a service, if any at all. In most cases it is the role of the DTC to agree the service. If the approval process is weak then trusts may implement home care services which are poorly designed, have weak contractual relationships, financial systems and may contain unnecessary potential clinical risks.

Many current homecare services that are being offered are low in clinical support and are predominantly supply focussed. There are visible signs that this trend is changing. Trusts due to pressure on their budgets are now looking to rationalise their clinical offerings and provide more clinically oriented services in the patient's home. The current fairly limited control of the product distribution and service specification may not be appropriate for future purposes.

Approval process for products and services

The development of more clinical homecare services requires further managed control systems. For example, the minimum benefits of each Homecare product/service should be ascertained and recorded from a local, regional and national perspective to ensure that the NHS only offers the service for legitimate reasons.

A structured process which would include using a nationally agreed documentation would ensure that a common high standard of governance would be in place locally. This documentation would incorporate the specification work from the NHMC, plus include additional product and service specific information. Agreement or approval by the NHS would need to take place at national level before such a homecare services could be provided.

Such a national approval or kite mark process should be developed for each homecare service prior to local implementation, broadly similar to current PASLU schemes in operation. The approval/kite mark process would involve a multi-disciplinary team of NHS experts who would consider the appropriateness of any proposed documentation and system. The purpose of such an approval process would be to ensure that there would be a common high standard of service design. The review of such a service would take into account the financial, pharmaceutical and clinical governance elements of the scheme. Close collaboration with regulatory and other agencies will be the key to this success e.g. MHRA, CQC, NHMC, Monitor.

Also, a simple recording system of all home care services that are implemented locally by individual trusts should be recorded, preferably on a web-based system. This will ensure that only approved homecare services that have been authorised are being provided. The data could be of additional benefit by providing more information on development of the homecare market so that any change can be established and considered at strategic and policy level.

Allan Karr
March 2011



Glossary of Terms

8

Name	Acronym	Description
Acute services		Medical and surgical interventions usually provided in hospital. Specific care for diseases or illnesses that progress quickly, feature severe symptoms and have a brief duration.
Association of the British Pharmaceutical Industry	ABPI	The Association of the British Pharmaceutical Industry (ABPI) has 150 members including the large majority of the research-based pharmaceutical companies operating in the UK, both large and small. Member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the National Health Service (NHS).
Ascribe		Ascribe provides a range of IT solutions to Primary and Secondary Care Pharmacies. These solutions focus upon delivering improved healthcare to patients, and are scalable, allowing single unit/site installations to Trust wide roll-outs. They are one of around 8 companies which provide a stock control pharmacy system as well as medicines management and ePrescribing within the hospital setting. See www.ascribe.com .
British Generic Manufacturing Association	BGMA	The British Generic Manufacturers Association (BGMA) represents the interests of UK-based manufacturers and suppliers of generic medicines and promotes the development and understanding of the generic medicines industry in the United Kingdom.
Board of Commissioners	BOC	Route for PCT to gain agreement jointly.
Benefits Tracking Tool	BTT	BTT data warehouse and integrated reporting tool.
Care Quality Commission	CQC	Regulate care provided by the NHS, local authorities, private companies and voluntary organisations. They aim to make sure better care is provided for everyone - in hospitals, care homes and people's own homes. They also seek to protect the interests of people whose rights are restricted under the Mental Health Act.
Chief Executive Officer	CEO	
Combined Panel		Review panel consisted of Mark Hackett, as Chair, Steering group and Working group.
Commercial Medicines Unit	CMU	CMU work to ensure that the NHS in England makes the most effective use of its resources by getting the best possible value for money when purchasing goods and services. CMU enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.

Glossary of Terms

Name	Acronym	Description
Commissioning for Quality and Innovation	CQUIN	The Commissioning for Quality and Innovation (CQUIN) payment framework enables commissioners to reward excellence by linking a proportion of providers' income to the achievement of local quality improvement goals.
Department of Health	DH	
District Health Authorities	DHA's	
Drug and Therapeutics Committee	DTC	
Electronic Prescribing Analysis and Cost	e-PACT	A service for pharmaceutical and prescribing advisors, which allows real time on-line analysis of the previous sixty monthsThe prescribing data, held on NHS Prescription Services' Prescribing Database
Family Health Service Authority	FHSA's	
General Practitioner	GP	
General Medical Services	GMS	
General Pharmaceutical Council	GPhC	The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain.
Healthcare Resource Groups	HRG's	
Home Parenteral Nutrition	HRG's	
Home Parenteral Nutrition	HPN	
High Cost Drugs	HCD	
JAC		JAC provides a single integrated solution along with associated services and third-party interfaces. They are one of around 8 companies which provide a stock control pharmacy system, as well as medicines management and ePrescribing within the hospital setting. See www.jac-pharmacy.co.uk .
Key performance indicators	KPI'S	Key Performance Indicators are quantifiable measurements, agreed to beforehand, that reflect the critical success factors of an organisation.
Manufacturer derived scheme		Process by where the manufacturers of the product works with a homecare provider to ensure their product/s are delivered to a patient at home. The NHS has no relationship or involvement with this arrangement other than paying for the product and service which is bundled together.

Name	Acronym	Description
Manufacturers Licence	ML	Process by where the manufacturers of the product works with a homecare provider to ensure their product/s are delivered to a patient at home. The NHS has no relationship or involvement with this arrangement other than paying for the product and service which is bundled together.
Medicines and Healthcare products Regulatory Agency	MHRA	An executive agency of the Department of Health. Enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe. No product is risk-free. Underpinning all the work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.
Monitor		Monitor authorises and regulates NHS foundation trusts and supports their development, ensuring they are well-governed and financially robust.
Multi-disciplinary team		Collaborative efforts of professionals from different disciplines toward a common goal. Can be made up of Consultant's, Clinician's, Nurses, Pharmacists and Healthcare Workers.
National Clinical Homecare Association	NCHA	Represents and promotes the interests of industries whose business is substantially to provide medical supplies and/or clinical services directly to patients in the community within an appropriate quality framework. Provide a forum for lobbying on issues that affect homecare. Set and debate policy decisions with the National Homecare Medicine Supply Committee and other relevant government bodies.
National Health Service	NHS	
National Health Service Quality Assurance Staff	NHS QA staff	Facilitated and managed by Commercial Medicine Unit. NHMC formed to develop appropriate systems, policies and procedures in order to assist service users, service providers and patients.
National Patient Safety Agency	NPSA	Lead and contribute to improved, safe patient care by informing, supporting and influencing organisations and people working in the health sector. An Arm's Length Body of the Department of Health and through three divisions covers the UK health service.
National Pharmaceutical Supply Group	NPSG	Provides advice to Chief Executive, CMU, concerning the cost effective purchasing and distribution of pharmaceutical products to the NHS in England. Acts as a focal point for the NHS for pharmaceutical issues of a national nature and provide pharmaceutical advice accordingly. Acts as a link between pharmacists and CMU at national level. Advises the Department of Health and pharmaceutical industry on significant commercial matters.

Glossary of Terms

Name	Acronym	Description
National Institute for Health and Clinical Excellence	NICE	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.
National Reporting and Learning Service	NRLS	National safety reporting system. Receive confidential reports of patient safety incidents from healthcare staff across England and Wales. Clinicians and safety experts analyse these reports to identify common risks to patients and opportunities to improve patient safety.
Official Journal of the European Union	OJEU	The Official Journal of the European Union is the central database for European public sector tender notices.
Payment by Results	PbR	
Primary Care Trust	PCT	Community patient care.
Pharmaceutical Price Regulation Scheme	PPRS	A British mechanism for determining the prices the NHS pays for brand name drugs.
Pharmaceutical Market Support Group	PMSG	Committee of pharmacists from England, Wales, Northern Ireland and Scotland. A representative from each purchasing group or division makes up the English representation. Provide strategic advice to the pharmaceutical industry and contracting groups. The PMSG use market intelligence including Phate analyses and licence and patent information.
Pharmex		<p>A medicines database which electronically collates pharmaceutical purchasing data of NHS hospital trusts in England. The system supports the management and tendering process for pharmaceutical contracts and helps provide a comprehensive overview of medicines usage in secondary care.</p> <p>In addition to its original objectives, the 54 million lines of data are used in support of DH initiatives such as monitoring of secondary care expenditure for PPRS and in providing increased visibility in the management of pharmaceutical supply issues.</p>
Purchasing Authority		Secondary Care Trusts, Primary Care Trusts, Foundation Trusts, Collaborative Procurement Hubs and Confederations.
Quality, Innovation, Productivity and Prevention	QIPP	QIPP is a large scale transformational programme for the NHS, involving all NHS staff, clinicians, patients and the voluntary sector and will improve the quality of care the NHS delivers whilst making up to £20billion of efficiency savings by 2014-15, which will be reinvested in frontline care.
Regional Quality Control	Regional QC	

Name	Acronym	Description
Serious Untoward Incidents	SUI's	An SUI is in general terms something out of the ordinary or unexpected, with the potential to cause serious harm and/or likely to attract public and media interest that occurs on NHS premises or in the provision of an NHS or a commissioned service.
Service Level Agreement	SLA	A service level agreement (frequently abbreviated as SLA) is a part of a service contract where the level of service is formally defined. In practice, the term SLA is sometimes used to refer to the contracted delivery time (of the service) or performance.
Strategic Health Authority	SHA	
Sub-contractor		A subcontractor is an individual or in many cases a business that signs a contract to perform part or all of the obligations of another's contract. A subcontractor is hired by a general contractor (or prime contractor) to perform a specific task as part of the overall project.
Value Added Tax	VAT	
Value for Money	VFM	



Acknowledgement

National Prescribing Centre

The National Prescribing Centre (NPC) is responsible for helping the NHS to optimise its use of medicines. NPC is part of the National Institute for Health and Clinical Excellence (NICE), an independent organisation providing national guidance on promoting good health and preventing and treating ill health.

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