Scottish Government Pharmacy and Medicines Division on Homecare Medicines Services – Written evidence (HMS0008)

Key Messages

- A significant proportion of medicines homecare services are commissioned by medicines manufacturers. As part of the medicine price, homecare delivery is offered as a benefit to hospitals at no extra cost; this is commonly referred to as a 'bundled' price. Separating the product and service costs ('unbundling') could enable the NHS to use NHS procurement mechanisms to better manage the medicines homecare market including ensuring that opportunities for individual providers are at sufficient scale in areas such as the Highlands to enable investment in logistics and nursing capacity to better meet the needs of patients.
- The current VAT arrangement for contracted out services results in a comparative VAT benefit for hospitals from using outsourced providers. Changes to the VAT arrangements would enable alternative options for service provision, such as direct NHS delivery services. It would also ensure that the NHS is incentivised to use the most cost-effective supply route.
- The Scottish Government has commissioned a review of approaches to supply secondary care-initiated medicines and associated care to patients in the community in Scotland. The review will run from July to December 2023. The Scottish Government would welcome UK collaboration on solutions to market problems.

Background: Medicines Homecare in Scotland

The term medicines homecare is used to describe the on-going supply of medicines and where necessary associated care, initiated by a hospital prescriber, direct to a patient's home. Medicines homecare services are utilised by all 14 territorial health boards in Scotland to provide around 38,000 patients with secondary care prescribed medicines. The total NHS Scotland spend on medicines supplied via medicines homecare services is estimated at ~£275m in 2022/23.

The majority of services are considered to be 'low-tech' (dispensing and delivery) or 'mid-tech' (dispensing, delivery and device training) with a small number of specialised 'high tech' services, for example administration of an infusion in the patient's home.

The medicines homecare market has grown rapidly over the past 20 years; benefits include offering patients' convenience compared to

collecting medicines from hospital pharmacies and releasing both clinical service capacity and hospital pharmacy capacity. Under the current VAT arrangements, there is a financial benefit to hospitals from use of outsourced providers; if a hospital pharmacy supplies an out-patient medicine, VAT applies, whereas, if a private sector pharmacy supplies the same medicine, the transaction is zero-rated.

A significant proportion of homecare services are commissioned by medicines manufacturers. As part of the product price, a manufacturer may offer homecare delivery as a benefit at no extra cost; this is commonly referred to as a 'bundled' price. Under this model, the NHS continues to take clinical responsibility, but the manufacturer selects, contracts and funds the homecare provider. The Health Board may have no or very limited choice of provider.
Whilst there has been significant collaboration between the NHS and industry in recent years to try to improve standardisation of service specifications, the arrangements for each manufacturer-commissioned service varies. Examples include variability in the commissioned provider(s), patient eligibility criteria, the funded frequency of deliveries and whether any required ancillary items are to be supplied by the provider. Where a manufacturer has commissioned multiple providers, there are differences between each provider's arrangements for the same product, including choice of delivery days, how deliveries are scheduled and whether the delivery will be made by the provider's own fleet of vehicles, a contracted courier or Royal Mail. There is a single standard Service Level Agreement (SLA) in place between Health Boards and each provider with the arrangements specific to each manufacturer-commissioned service set out in product specific appendices to the SLA. There are over 200 SLA appendices in place in Scotland each detailing different product specific service arrangements. This complexity creates significant workload for the NHS and providers to manage with product-specific prescription form templates often required.

NHS National Procurement, part of NHS National Services Scotland, leads the NHS commissioning of homecare services on behalf of Scotland's health boards. The NHS Scotland Low and Mid-Tech Medicines Homecare Services Framework covers a broad range of medicines where the service requirement is either dispensing and delivery or dispensing, delivery and device training. Unlike manufacturer-commissioned homecare, this Framework provides flexibility to the NHS to choose the provider that best meets their needs. Additional medicines can be efficiently added to the standard NHS contracted arrangements as long as the service requirement is in line with the commissioned service specification.

There are also NHS commissioned Frameworks covering the supply of parenteral nutrition, peritoneal dialysis, blood clotting factors and enzyme replacement therapy.

Barriers to Competition

Barriers to providers entering and competing in the market include requirements for a high degree of capital given the cost of the medicines concerned and incumbency advantages linked to the disruption and cost of change involved in changing provider. Economies of scale are essential to the current homecare business model; in late 2013 Medco Health Solutions exited the market after a number of years, in-part because they were not able to reach a profitable scale quickly enough. Providers also face challenges in securing supply of medicines at NHS contract pricing from manufacturers.

Improving digital connectivity between the NHS and providers has the potential to improve operational efficiency but unless there is standardisation of approach within the market, there is a significant risk this becomes a further barrier to competition.

Service Problems and the Impact

Over the past 10 years, all major homecare providers have experienced periods of capacity constraints and service issues. This has been particularly acute over the past 3 years driven by COVID-19 related absence, challenges with recruitment and retention, and a lack of flexibility in the capacity within homecare providers to respond to fluctuations in workload, for example managing short-term disruption in medicines supply that requires providers to arrange extra deliveries. When problems arise, the situation can quickly deteriorate; for example managing the increase in patient calls enquiring about delayed deliveries can reduce capacity to proactively contact patients to support scheduling deliveries. Sudden unplanned changes in service commissioning, for example manufacturers terminating contracts with an affected provider can create surges in demand for other providers and have a knock-on impact in the wider market.

Service issues have led to some patients missing doses, led to delays in treatment initiation and caused considerable stress and anxiety for patients. This has created significant workload for both pharmacy and clinical teams within Health Boards who have worked to minimise the impact on patients, for example arranging supply through NHS supply routes.

Performance Management

Performance management against agreed service levels takes place at a number of levels within the NHS:

- Health Boards engage directly with providers on any localised problems arising.
- NHS National Procurement in partnership with Health Boards, has formal review meetings with providers at NHS Scotland level, with the frequency arranged based on severity of the issues being experienced; and
- A subgroup of the National Homecare Medicines Committee (NHMC) leads performance management of homecare providers at UK level with an agreed escalation process in place.

Performance management reviews consider a wide range of information including complaints and incidents arising, feedback received from clinical teams and routinely reported Key Performance Indicators (KPIs). Over the past 10 years, there has been significant work to standardise KPI reports at UK level to allow benchmarking of provider performance. The NHMC is currently reviewing the national KPI set to ensure that data collected is as meaningful as possible to monitor performance.

When service problems arise, there is work with providers to agree an action plan and then close monitoring of the delivery of performance improvements against that plan until service levels return to agreed standards. In discussions, consideration is also given to actions that the NHS can take to support the provider in improving service levels. A key area for development is improving digital connectivity between the NHS and providers.

As pharmacies, medicines homecare providers must demonstrate that they can meet the standards for registered pharmacies set by the pharmacy regulator, the General Pharmaceutical Council (GPhC). The standards are designed to create and maintain the right environment for the safe and effective practice of pharmacy and to improve the quality and safety of services provided to patients and the public. Depending on the range of services provided, medicines homecare providers may also be registered with additional regulators, for example the Care Inspectorate in Scotland if nursing services are provided.

There are a range of barriers to switching providers including capacity constraints in the market and disruption for patients and workload for clinical teams in managing switches. There is often limited alternative options where the manufacturer has commissioned the service and given geographical variation in the service levels provided by the various homecare providers, it may not be feasible to use alternative providers. The consequence is limited scope to use competition to drive improvements in performance.

Patient Expectations and Ensuring Clinical and Patient Understanding of Service Arrangements

A consequence of the current commissioning arrangements is that a single hospital clinic often has to work with different providers depending on the medicine being prescribed and be aware of medicine-specific variations in service arrangements. For example, some manufacturer-commissioned services are restricted to patients using the medicine for a licensed clinical indication therefore if the patient requires the medicine for an 'off-label' use to meet that patient's individual clinical need, NHS commissioned arrangements must be used. Errors caused by this complexity can lead to delays in the supply of medicines.

There are inevitable time lags in homecare providers on-boarding patients to a new service. Whilst homecare services were originally intended for patients who were stable on treatment, they are now commonly used from the point of a patient being initiated on a new therapy with manufacturer-commissioned services often including funded device training for injectable medicines. The VAT arrangements create a financial incentive to supply via outsourced providers from the point of initiation.

Community Pharmacy as an Alternative Approach

A 2013 independent review of NHS pharmaceutical care of patients in the community in Scotland, carried out by Dr Hamish Wilson and Professor Nick Barber, raised concerns about the potential for direct supply of specialist items by homecare providers to fragment care. With a focus on optimising pharmaceutical care, in recent years, there has been work to pilot the supply of secondary care initiated medicines through community pharmacies in Scotland.

Research in NHS Tayside and NHS Greater Glasgow and Clyde on the use of community pharmacies to dispense specialist medicines including antivirals to treat Hepatitis C and oral prostate cancer medicines (abiraterone and enzalutamide) found this could be carried out safely and effectively, improving patient experience and overall care. This has enabled community pharmacies to play a more informed and important role in the supply and management of the care of these patients. In the case of the antivirals, this pathway helped increase treatment uptake in hard-to-reach groups.

Whilst this work has demonstrated clear benefits from greater use of community pharmacies, it has also highlighted a range of challenges including the impact this has on pharmacy cash-flow due to the high purchase cost of many of the medicines traditionally supplied through medicines homecare.

Barriers to Alternative Supply Routes

Barriers to progressing the development of alternative supply routes include the VAT arrangements and the practice of bundling of homecare service costs into the medicine price.

In August 2020, HM Treasury consulted on refunding all VAT incurred by NHS bodies in relation to their non-business activities with a corresponding reduction in budget. Removing the comparative VAT benefits of using an outsourced provider for the supply of medicines to patients, would enable alternatives to homecare to be explored, for example direct delivery services by the NHS or to overcome community pharmacy cash-flow challenges, the potential for central purchasing of specialist medicines by the NHS for supply to pharmacies free of charge for onward dispensing to patients, a model that has been adopted in the Republic of Ireland.

The second key barrier is the practice of service costs being bundled into the medicine price. A key recommendation from the 2011 Department of Health commissioned review of the medicines homecare market undertaken by Mark Hackett was that, "The NHS should pursue an immediate unbundling of homecare medicine dispensing, delivery and associated service costs [from the medicine price]. The pharmaceutical suppliers and the NHS should define these costs and reduce them from their current prices". Where the service costs are bundled into the product price, it would cost the NHS more to adopt an alternative service arrangement as the same price for the medicine would apply, regardless of whether the manufacturer-commissioned homecare service is used, and the NHS would need to fund the service costs of the alternative supply arrangement.

Unbundling could enable the NHS to use NHS procurement mechanisms to better manage the medicines homecare market including ensuring opportunities for individual providers are at sufficient scale in areas such as the Highlands to enable investment in logistics and nursing capacity to better meet the needs of patients. Unbundled medicine pricing would ensure that the NHS is appropriately incentivised to use the most cost-effective supply route.

Over the past 5 years, NHS National Procurement has actively engaged with companies and sought to 'unbundle' in a number of therapy areas including off-patent biologic medicines. Through product tenders, both bundled and unbundled prices were sought. There has been limited success. Feedback from companies has been that manufacturer-commissioned homecare offers benefits to the company including supply chain control and granularity of data on medicines sales. As there was not a consistent approach to seeking unbundling across the UK, some manufacturers have been reluctant to have a different supply arrangement in Scotland.

The Scottish Government has commissioned a review of approaches to supply secondary care-initiated medicines and associated care to patients in the community in Scotland. The Scottish Government would welcome collaboration with other administrations and stakeholders on solutions to market problems.

26 June 2023