NHMC

National Homecare Medicines Committee

Good Practice Principles:

Provision of Manufacturer Funded Homecare Medicines Services

National Homecare Medicines Committee
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Version 1

Definitions

Term	Definition
Clinical Referring Centre	Any organisation that refers patients to a Homecare Provider to receive a Homecare Medicines Service
Clinical Teams	Clinical staff responsible for the prescribing of medicines including, but not limited to, Consultants, Nurse Specialists, Nurse Prescribers or Pharmacist Prescribers
Commissioner	The ultimate funder of the product and/or Homecare Medicines Service; typically, NHS England or a local Clinical Commissioning Group
Core Homecare Medicines Service	Dispense and delivery of medicines to a patient's home with or without injection training by a Homecare Provider's nurse
Homecare Medicines Service	A service that delivers ongoing medicine supplies and where necessary associated care, typically initiated by a hospital prescriber, direct to a patient's home with their consent. The purpose of the homecare medicines delivery service is to improve patient care and increase their choice of location for their clinical treatments
Homecare Provider	The legal entity responsible for co-ordinating the delivery/and or administration of the medicine to the patient in their home, or other suitable location
Manufacturer	The Marketing Authorisation Holder of a pharmaceutical product (medicine / device)
Manufacturer Funded Homecare Medicines Services (Also referred to as pharma funded homecare or pharma schemes)	Homecare Medicines Services for which one or more Homecare Providers are funded by a manufacturer of a Medicine/device (pharma company) to provide a Homecare Medicines Service to NHS patients.
National Homecare Medicines Committee (NHMC)	The NHMC is the lead NHS committee responsible for the development and management of Homecare Medicines Services to NHS patients
NHS Standard Homecare Medicines Services Specification	A standard description of service levels based on the Homecare Medicines Services Template Specification[1]
Patient Support Programme (PSP)	An organised system where a marketing authorisation holder receives and collects information relating to the use of its medicinal products. Patient Support Programmes include post authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information gathering

[1] Homecare Medicines Services Template Specification: https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services

	on patient compliance, or compensation/re-imbursement schemes.[2]
Pharmacy Homecare Teams	Specialist pharmacy staff, commonly comprising of a mix of pharmacists, pharmacy technicians and pharmacy assistants, who manage the operation of Homecare Medicines Services under the authority of the Chief Pharmacist

Introduction

These Good Practice Principles set out the National Homecare Medicines Committee's (NHMC) expectations of Manufacturers offering Manufacturer Funded Homecare Medicine Services in relation to the supply of a medicine/device.

Providing clarity of these expectations is intended to promote positive development of the relationship between the NHS and Manufacturers to serve the best interests of NHS patients and stakeholders.

Manufacturers are encouraged to endorse these Good Practice Principles during the development and commissioning of their Homecare Services and thereby demonstrate their commitment to work collaboratively with Clinical Referring Centres to provide a high-quality service and experience to NHS patients.

For the avoidance of doubt, neither this document nor subsequent Manufacturer endorsements of the principles contained herein are intended to constitute a legally binding agreement.

Statement of Principles

1. Contractual Arrangements

1.1 Manufacturers should hold an appropriate contract with each Homecare Provider selected to provide the Manufacturer Funded Homecare Medicines Service.

1.2 Manufacturers should offer a minimum of two different Homecare Providers for each Manufacturer Funded Homecare Medicines Service wherever possible and appropriate.

This provides flexibility and choice to Clinical Referring Centres and contingency in the event that, for whatever reason, a Homecare Provider cannot provide the service either in whole, in part or to an acceptable standard.

[2] European Medicines Agency Home – Regulatory - Human medicines – Pharmacovigilance - Good pharmacovigilance practices
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC500172402.pdf

1.3 Manufacturers should aim to utilise the Homecare Provider(s) as the primary contractor with any other parties involved in the service delivery acting as a sub-contractor to the primary contractor.

This minimises administrative burden to the Clinical Referring Centre, expedites service initiation and simplifies contract management.

1.4 Manufacturers should ensure that the service specification is cognisant of, and wherever possible and appropriate, aligned with the NHS Standard Homecare Medicines Services Specification.

It is recognised that Manufacturers are bound to comply with prevailing regulation beyond the scope of the NHS Standard Homecare Medicines Services Specification.

1.5 Manufacturers should ensure their service specification is available to the Clinical Referring Centre either directly or via the selected Homecare Provider(s).

This provides clarity to the Clinical Referring Centre allowing, where necessary, the Clinical Referring Centre to determine and agree with the Homecare Provider any service enhancements required.

1.5.1 The Manufacturer's service specification should include, but is not limited to, details of:

- timelines for making first contact with patient (both for deliveries and, if appropriate, training/ education);
- delivery windows;
- delivery frequency;
- management and replacement of faulty medicines/devices;
- funding of unused medicines/devices;
- emergency delivery charges.

1.6 Manufacturers should support the use of national standard documents and procedures, developed by the NHMC, within Manufacturer Funded Homecare Medicines Services.

1.7 Patient Support Programmes (PSP) should be detachable from the Core Homecare Medicines Service.

This provides appropriate flexibility to allow opt out from the PSP either by the Clinical Referring Centre at contract level or by individual patients.

1.8 Development and provision of Manufacturer bespoke IT platforms (e.g. customer portals for patient registration and ePrescribing) is not normally recommended nor endorsed by the NHMC.

This is to minimise the risk of over localisation of system solutions. The NHMC is working with NHS Digital and engaging with other systems providers in pursuit of a single common system for use across all Homecare Medicines Services.

1.9 Clinical Referring Centres are responsible for ensuring that they have an appropriate contract in place with their selected Homecare Provider prior to commencement of Manufacturer Funded Homecare Medicines Services.

Where a Manufacturer Funded Homecare Medicines Service is available from two or more Homecare Providers, the Clinical Referring Centre will commonly select one of those Homecare Providers to deliver service to their patients.

1.10 Manufacturers are not expected to play any enforcement role in the contractual relationship between a Clinical Referring Centre and their selected Homecare Provider. However, it is recognised that, as the Homecare Medicines Services funder, the Manufacturer has a level of leverage on the Homecare Provider in relation to service performance. The Clinical Referring Centre may communicate significant Manufacturer Funded Homecare Medicines Services issues to the Manufacturer for information.

1.11 Manufacturers should consider the specific governance requirements of community pharmacy collections prior to their inclusion in the Manufacturer Funded Homecare Medicines Services specification and such services should remain detachable from the core Homecare Medicines Service offered.

1.12 Manufacturers should work collaboratively with Clinical Referring Centres to ensure that the delivery frequencies offered takes into consideration risk of medicines wastage, which has a financial impact to Clinical Referring Centres as well as cost of service to the Manufacturer.

1.12.1 Manufacturers should work collaboratively with Clinical Referring Centres to make appropriate arrangements to ensure delivery frequencies align with local requirements set by the Commissioner.

2 <u>Communication</u>

General

2.1 Manufacturers are strongly encouraged to liaise with the NHMC prior to communication of any new, or notable changes to existing, Manufacturer Funded Homecare Medicines Services or Patient Support Programmes with Clinical Referring Centres or NHS patients.

The NHMC can provide a high level advisory role and, where appropriate, can cascade information to Clinical Referring Centres via regional representatives to support the Manufacturer's communication plan. Engagement should be via the NHMC Chair.

New Services

2.2 Wherever possible, Manufacturers should provide the NHMC at least three months' notice of any new Manufacturer Funded Homecare Medicines Services or Patient Support Programmes. Notice should be directed to the NHMC Chair.

This ensures that there is sufficient time for:

a) the NHMC to identify and discuss with the Manufacturer any anticipated barriers, challenges or other considerations in relation to planned services or programmes;

b) the Clinical Referring Centres to establish contractual relationships with their selected Homecare Provider and implement services safely.

Service Change

2.3 Wherever possible, Manufacturers should provide the NHMC at least three months' notice of any notable changes to existing Manufacturer Funded Homecare Medicines Services or Patient Support Programmes. Notice should be directed to the NHMC Chair.

This ensures that there is sufficient time for:

a) the NHMC to identify and discuss with the Manufacturer any anticipated barriers, challenges or other considerations in relation to planned service or programme changes;

b) the Clinical Referring Centres to appropriately amend the contractual relationship with their selected Homecare Provider and implement changes safely;

c) the Clinical Referring Centres to transition patients to another Homecare Provider where relevant.

2.3.1 Notable changes include, but are not limited to, those that have a potential impact on;

- Patient experience
- Administrative burden to Clinical Referring Centres
- Finances of Clinical Referring Centres

2.3.2 Specific importance is given to early notification of intention to withdraw funding from a Manufacturer Funded Homecare Medicines Service, either in full or from one or more Homecare Providers. In these circumstances, Manufacturers should, whenever possible, provide the NHMC at least six months' notice.

Local

2.4 The Chief Pharmacist is the Responsible Officer for Homecare Medicines Services in the Clinical Referring Centre. Operational management of Homecare Medicines Services typically resides with Pharmacy Homecare Teams.

2.5 Manufacturers, and their contracted Homecare Providers, should aim to discuss any available Manufacturer Funded Homecare Medicines Services or Patient Support Programmes with the Pharmacy Homecare Team prior to any engagement with Clinical Teams at the Clinical Referring Centre.

Where there is an absence of response from the Pharmacy Homecare Team, it is considered appropriate, with respect to 2.6 below, for Manufacturers, and their contracted Homecare Providers, to approach Clinical Teams directly.

2.6 Manufacturers, and their contracted Homecare Providers, should aim to ensure Pharmacy Homecare Teams are invited to all meetings where homecare arrangements or Patient Support Programmes are discussed with the Clinical Referring Centre.

In practical terms, this means that Pharmacy Homecare Teams should, as a minimum, be aware of such meetings prior to them taking place; able to attend or otherwise participate as appropriate.

Service Performance

2.7 Where appropriate, the Manufacturer should notify the NHMC, or individual Clinical Referring Centres, where declining trends are identified in the performance of their contracted Homecare Provider(s). In particular the Manufacturer should notify the NHMC where such declining trends can be reasonably considered to compromise patient safety.

2.8 Where appropriate, the NHMC, or individual Clinical Referring Centres, should notify the Manufacturer where declining trends are identified in the performance of a Homecare Provider. In particular the NHMC, or individual Clinical Referring Centres, should notify the Manufacturer where such declining trends can be reasonably considered to compromise patient safety. With respect to any significant service issues communicated to the Manufacturer by the Clinical Referring Centre pursuant to paragraph 1.10, the Manufacturer should review such concerns and take appropriate action where relevant in the Manufacturer’s reasonable opinion.

3 Continuity of Supply

3.1 Manufacturers should have alternative medicines supply routes available as contingency in the event that the Homecare Provider(s) terminates their agreement or is unable to provide the service to an acceptable standard.

3.1.1 Alternative supply routes may include other Homecare Providers, direct supply or pharmaceutical wholesalers supply of medicines to hospital pharmacy, outsourced outpatient pharmacy or community pharmacy where appropriate. For the avoidance of doubt, this section relates to continuity of supply of the medicine and not necessarily the continuity of provision of the Homecare Medicines Service.