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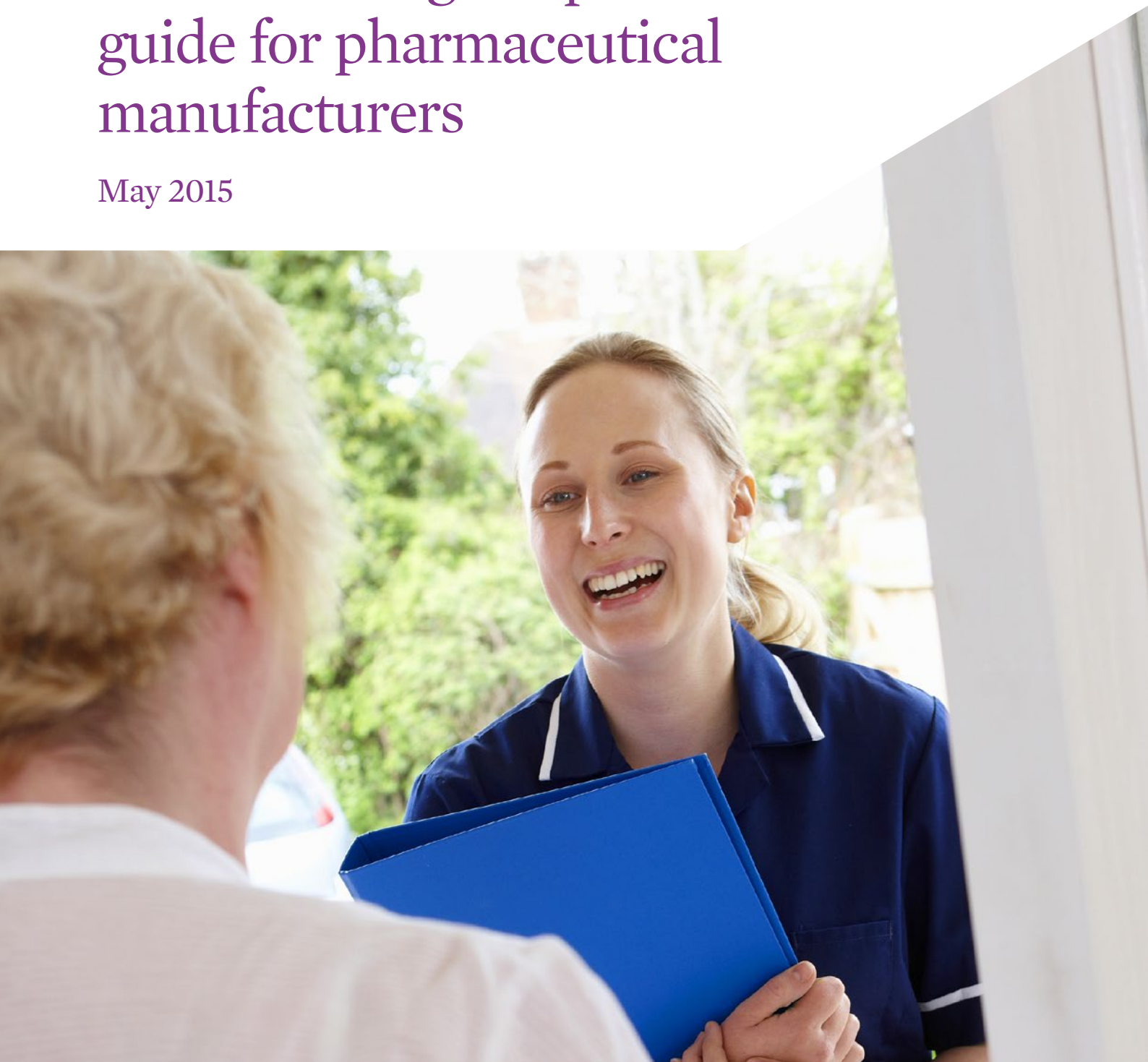
Homecare: a good practice guide for pharmaceutical manufacturers

May 2015



Introduction

When homecare is chosen as an appropriate means for medicines distribution, it is key that the supply of the services is well thought out in advance, that all parties understand what is required of them and that contingency arrangements are in place. Pharmaceutical companies take the provision of homecare services seriously, and although practice will vary between companies, in what is a commercial arena, there are a number of principles and legislative requirements which can be distilled into a good practice guide.

This guide attempts to pull together these principles via a series of issues to be considered by companies. Although it focuses on the needs and actions for the manufacturer, it may also be of interest to a range of stakeholders involved in homecare services, including clinicians, pharmacy, NHS Finance, NHS Procurement Governance, homecare providers, the Commercial Medicines Unit, commissioners, members of the National Homecare Medicines Committee and patients.

However, this guide is not intended as a definitive or comprehensive manual for how homecare arrangements are designed, contracted or managed by the pharmaceutical industry, as such arrangements need to be decided unilaterally by manufacturers on a case-by-case basis.

This guide is structured to align with the Royal Pharmaceutical Society's (RPS) Professional Standards for Homecare Services and their Handbooks for Homecare Services (see Annex 1 – Useful links) and is to be seen as a living document, recognising the need for future useful documentation to be added and referenced.

The patient experience

Patients remain at the heart of any homecare service. This section aims to highlight the key areas for manufacturers to consider in relation to patients when considering the design and establishment of a homecare service.

Whether it is appropriate for individual patients to receive their medicine and/or additional services, or care, at home must be determined by a healthcare professional in consultation with the patient.

Patients may need to be transferred to, or from, a homecare service, or between homecare providers, at any time during the course of their treatment, and services must be designed to allow this to happen with minimum impact on the patient.

Patients will be asked by their Trust to sign an initiation document which indicates their consent to receiving a homecare service and their acknowledgement that they have received appropriate information. More information regarding service initiation is available in the RPS Handbooks for Homecare Services (see Annex 1 – Useful links).

Patient choice

Under the NHS Constitution (see Annex 1 – Useful links) patients in England have the right to a certain amount of choice in their care. Patient choice includes whether the patient wants to opt in or out of an available homecare service, and to some extent, at what date, time and location their medicines and or services will be delivered.

Where a patient receives more than one medicine from multiple manufacturers, every reasonable attempt should be made by the manufacturer to enable the homecare provider to consolidate deliveries.

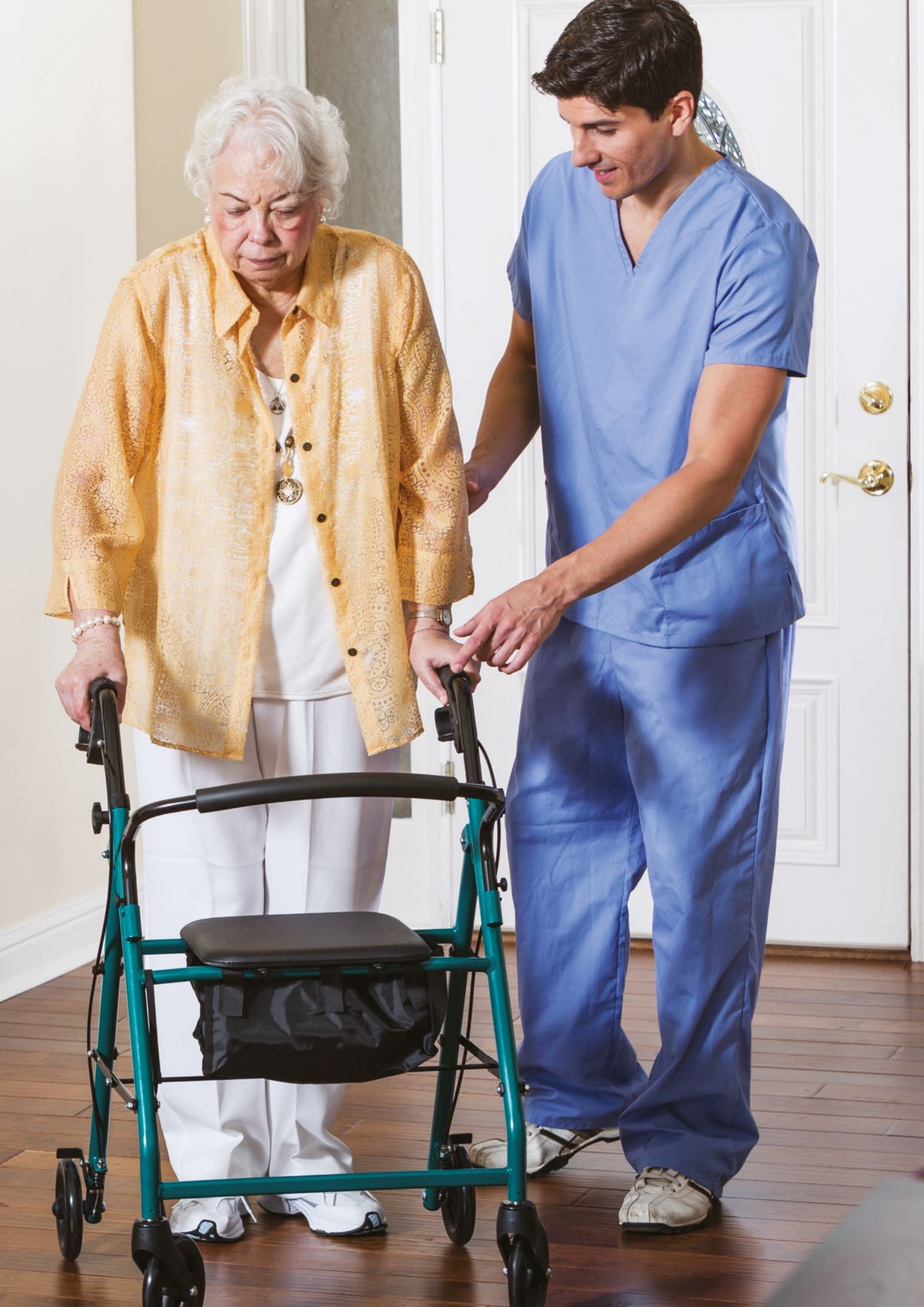
It is the responsibility of Trusts that patients should be made fully aware of their rights, ideally by providing them with a copy of the Homecare Medicines Patient Charter which can be found in the RPS Handbooks for Homecare Services.

Manufacturers may also wish to assure themselves that the patient is made aware of how the homecare service is likely to operate, provided with appropriate information about their medicines (e.g. patient information leaflets), understands the patient's own responsibilities, and is given details of how they can opt out or make complaints.

Patient group engagement

Manufacturer engagement with relevant patient groups or third-sector organisations should be considered on an ongoing basis, to ensure any homecare service is fit for purpose.

Manufacturers may seek assurances that patients receiving a homecare service are regularly consulted via surveys from the homecare provider to ensure the quality and consistency of any service.



Implementation and delivery of safe and effective homecare services

Contractual framework for a homecare service

Before developing a contractual framework with homecare providers, it may be useful for manufacturers to consider early engagement and consultation with the National Homecare Medicines Committee regarding innovative homecare service initiatives. The questions below may provide a useful, if not comprehensive, aide memoire.

Product selection

Why are these products suited to homecare? Has this been discussed with patients, clinicians and commissioners?

Type of service

What type of service is to be provided?

Examples include:

- dispense and deliver only
- delivery with nurse administration
- more complex additional services such as infusion at home.

Who is the customer?

Trust/Commissioner/Primary care/Health board/Other health organisations

At what level will the service be provided?

Trust/Regional/National

Who will pay for the service?

Sometimes manufacturers pay, but other funding models are available – for example, the costs could be shared between a Trust and a manufacturer.

Is there already a service provided by the NHS?

Is there an existing homecare service in place?

Is the intention to replace an already available service or does the existing service not meet requirements?

Provider identification

Which providers have the capability to deliver the service?

Which provider(s) should be used? Is a sole or multiple provider service preferable?

A sole provider may be preferred because demand is likely to be relatively low, or to avoid a fragmented supply chain to ensure robust availability. Alternatively, a multiple supplier option may be preferable if high volume and/or continuity of supply are significant factors.

How many potential providers will be invited to participate in the selection process?

Companies are encouraged to invite a reasonable number (at least two or three) of potential providers to take part in the selection process. However, there is a risk of overcomplicating matters if companies invite too many providers to participate, and this should be taken into account.

Provider selection

Are you satisfied that the required level and quality of operational capability will be delivered?

For example:

- capacity to service patient population
- geographic coverage
- appropriate necessary professional qualifications and licences
- maintaining integrity of the supply chain
- understanding where legal recourse sits.

Homecare providers may vary in standards and it is recommended that capability audits are conducted, with tenders being issued for specific services and quality commitments. Manufacturers should satisfy themselves that the homecare provider can deliver the service that the company requires.

Have you conducted appropriate financial viability assessment?

For example, the risks will be considerable unless due diligence is completed before appointing a homecare provider.

Manufacturers should consider their position if there are reasonable grounds to question continuity of supply.

Have you selected the optimal quality thresholds to aid patient compliance and clinical outcomes?

For example:

- frequency of delivery
- nurse support
- patient education/training.

Assessment of proposals

Do you need to establish a cross-functional team to ensure appropriate consideration and inputs from various parts of the organisation?

For example: Commercial/Legal/Marketing/Procurement/Supply Chain/Quality Control/ Regulatory/Pharmacovigilance – all departments may have views to offer regarding each potential supplier's capability to deliver.

Award of the contract

Have the timelines been clearly communicated?

Will the homecare provider obtain supplies on a wholesale basis or direct from the manufacturer?

If contract prices are already in place, has the rebate process been detailed in the contract with the homecare provider?

Visibility of arrangements

Does your contract with the homecare provider ensure that a service level agreement (SLA) is shared between the provider and the relevant NHS organisation?

Have you given consideration to sharing your homecare scheme SLAs via the proposed dedicated NHS portal, when available, or with members of the National Homecare Medicines Committee?

Other agreements

Is there need for an additional confidentiality agreement between the manufacturer and the Trust?

Core service specification

The following core services are recommended to be specified in the manufacturer's overarching homecare agreement with providers:

- patient registration and confidentiality
- compliance/concordance monitoring and active feedback to hospitals to support patients' treatments
- dispensing and delivery
- administration of the product
- a detailed description of the services required for that product included in individual product agreements
- the right to audit homecare providers' adherence to service specifications, including any other manufacturer-specific audit requirements
- the mechanism by which pharmacovigilance and safety data must be communicated to the trust and the manufacturer
- management of complaints.

The Department of Health's Commercial Medicines Unit and a subgroup of the National Homecare Medicines Committee have developed a suite of service specifications for NHS purchasing authorities to adopt and utilise depending on the service contracted. Manufacturers may choose to adopt a similar approach, referencing the Homecare Medicines and Services Template Specifications listed in the RPS Handbooks for Homecare Services.

Homecare performance management service reviews

It is suggested that manufacturers assign appropriate resource to the management of contracted homecare providers, to ensure performance against contracts is optimally managed. It is suggested that manufacturers should hold regular service meetings with their contracted homecare provider to review performance against key performance indicators (KPIs), tracking trends and following any issues through to resolution. The timing of these reviews would be on a case-by-case basis; however, a timescale of at least quarterly would be recommended.

Manufacturers may consider the benefits of requiring homecare providers to issue patients with a questionnaire to survey their views on the quality of the service. Advice on health literacy may be available from appropriate patient organisations. After anonymisation, patient testimonials can then also be discussed at service reviews.

Core KPIs

KPIs are recommended to be included in any contracts that manufacturers have with homecare providers. These may include, but are not limited to aspects of:

- patient registration and service, e.g.
  - registration
  - dispensing overview
  - prescription overview
  - delivery overview
- safety and adverse event reporting, e.g.
  - complaints overview
  - adverse drug reaction overview
  - pharmacovigilance and safety training record management
- data reporting, e.g.
  - quality
  - timelines
  - financials.

The Department of Health's Commercial Medicines Unit and a subgroup of the National Homecare Medicines Committee have developed a core suite of KPIs for purchasing authorities to adopt and utilise depending on the service contracted. Manufacturers may choose to adopt a similar approach, referencing the suite of NHS KPIs listed in the RPS Handbooks for Homecare Services.

Risk management

There are a number of potential risks that manufacturers should be aware of, and aim to mitigate, when homecare services are put in place.

Where the NHS has tendered for homecare provision of a particular medicine, the manufacturer should expect to be contacted by the homecare provider(s) before they submit to the tender, in order to validate that tender requirements in relation to supply can be met. Subsequent distribution agreements are likely to include any terms relating to the provision of anonymised data to allow the manufacturer to effectively manage their supply chain. The manufacturer may also need to discuss expected usage volumes and increases to ensure accurate forecasting and supply chain integrity.

When manufacturers are supplying medicines to homecare providers for contracts they have successfully won from the NHS, they are encouraged to ensure that the homecare provider they are supplying to is adhering to the Professional Standards. See Accreditation (page 11).

Before entering into a trading agreement with any third party homecare provider, it is suggested that the manufacturer confirm the provider's financial viability by undertaking credit checks. A decision on whether to open a credit account or require the third party to pay upfront on a 'pro-forma' basis is at the discretion of the individual manufacturer.

When manufacturers are contracting homecare services they are advised to include in the contractual terms that the homecare provider must adhere to the Professional Standards for Homecare. See Accreditation (page 11).

Where a contract is being developed for a service between the manufacturer and homecare provider, consideration should also be given to the requirements of a technical agreement if the product is to be in any way altered, e.g. infusion services.

Where a hospital contract, discount price or Patient Access Scheme applies, the implementation and sharing of information need to be agreed between all parties, with any applicable non-disclosure agreements signed.

If a manufacturer encounters a shortage of supply, they should make the homecare provider(s) aware of the situation at the earliest opportunity. The NHS, manufacturers and providers should work together to ensure patients and clinicians are kept informed of the situation.

Where there are plans to transfer patients between homecare providers, consideration should be given to ensure that arrangements are in place for a seamless transition between homecare providers, to ensure patients experience no interruption in their care and their preferences are taken into account. It is likely that supporting communications will be needed between the NHS, homecare providers, manufacturers and patients. It should also be recognised that the planned transition needs to take place at a speed that allows appropriate governance to be set up and patient safety assured. It is recognised that on occasions, due to pharmacovigilance or contractual concerns, an urgent change in homecare provider is required. In such circumstances the commissioner of the service, i.e. either the manufacturer or the NHS, is encouraged to develop and implement a proactive and comprehensive stakeholder communications plan.

A risk management approach will safeguard the quality and provision of services to patients, and manufacturers may benefit from incorporating the principles of quality risk management into all aspects of homecare services in accordance with Quality Risk Management (ICH Q9).

Manufacturers are likely to require homecare providers to have robust business continuity management programmes and systems in place to the appropriate ISO standard, i.e. ISO 22301:2012.

Manufacturers should consider requiring that homecare providers operate and maintain a robust quality assurance procedure and methodology to ISO: 9001:2008, including a regular robust self-audit activity. It may be appropriate for manufacturers to request visibility of the self-audit plans and activity.

Manufacturers should ensure contracts clearly outline the homecare provider's responsibility in detailing with complaints. This may include contracted commitments that homecare providers deal with and respond to incidents in a timeframe that supports the NHS to respond to complaints within required timelines and compliance with any relevant Good Distribution Practice Responsible Person requirements. (For example, the Good Distribution Practice legislation was updated to 2013/C 343/01 in November 2013 to better describe the responsibilities of the Responsible Person named on the WDA. Section 6.2 of 2013/C 343/01 states: 'Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint.')

If elements (e.g. nurse educator provision direct to the patient) of a homecare service falls under the definition of a Patient Support Programme (PSP), manufacturers should ensure adherence to the necessary regulatory requirements: http://www.abpi.org.uk/our-work/library/guidelines/Pages/patient-safety-pharmacovigilance-.aspx.

Manufacturer business and workforce planning

It is recommended that manufacturers assign appropriate resource to the management of contracted homecare providers, to ensure performance against contracts is optimally managed.

Governance of homecare services

Royal Pharmaceutical Society (RPS) – Handbooks for Homecare Services

In 2011 the Department of Health commissioned the report *Homecare Medicines – Towards a Vision for the Future* (also known as the Hackett Report), led by Mark Hackett, formerly Chief Executive, University Hospital, Southampton NHS Foundation Trust. The report identified the Chief Pharmacist as the accountable officer for ensuring the safe and effective provision of homecare medicine services and made a list of recommendations to improve the financial and clinical governance arrangements for patients receiving medicines via the homecare route.

The implementation of this report included the development of national standards for homecare – RPS Professional Standards for Homecare Services and subsequently the Handbooks for Homecare Services. Manufacturers are strongly encouraged to consider the recommendations and examples of good practice captured in the Handbooks. These documents can be found at: http://www.rpharms.com/unsecure-support-resources/professional-standards-for-homecare-services.asp

Regulation and accreditation

Obligations under EU Law

Homecare is often selected as the route to fulfil product administration and monitoring obligations from the time when a medicine first becomes available for patients. The conditions of licensing a medicine require continued surveillance and data collection to ensure patient safety. In such instances the homecare provider may be selected by the manufacturer with a specific service specification in mind. A manufacturer could have its marketing authorisation revoked if they do not fulfil their post-marketing commitments (see Annex 2). In such circumstances, certain aspects of patient monitoring are not an additional service, but a legal obligation undertaken at a cost to the company.

Manufacturers are also required under Articles 23a and 81 of Directive 2001/83/EC (as amended) – within the limits of their responsibilities – to maintain appropriate and continued supplies of their products, and to notify the licensing authority if a product is not going to be available, either temporarily or permanently. The legislation requires two months' notice in all but exceptional circumstances. In addition to this requirement, manufacturers should ensure that the Department of Health is notified as soon as possible of any potential shortages that are likely to have an impact on patient care.

Pharmaceutical companies are also bound by competition law in their tendering and contractual activities within the NHS. Companies must decide their commercial practices unilaterally. This may result in companies requiring that pricing information, costs or any confidential information is not disclosed, in order that competition is not limited or distorted in any way.

Accreditation

Accreditation is not normally a formal process through a third party, but is more likely to refer to self-accreditation by the homecare provider to confirm its adherence to the Professional Standards for Homecare. The Professional Standards for Homecare include some definitions of homecare services types:

- low tech
- mid tech
- high tech
- complex care.

Homecare providers should be encouraged to self-accredit against each of these service types. Professional standards for the provision of complex homecare are outside the scope of the Standard.

Manufacturers are encouraged to ask for details of self-accreditation from the homecare providers that they contract to or supply with products.

Nurse qualification

Where nursing services are included as a component of the homecare arrangement, the manufacturer's medical department may consider how best to approve the specification details, including the appropriate qualification of the nurse undertaking the service.

Annex 1 – Useful links

'Managing homecare in the NHS: a collaborative approach':
http://www.abpi.org.uk/our-work/library/industry/Pages/130614.aspx

'Homecare Medicines – Towards a vision for the future':
http://media.dh.gov.uk/network/121/files/2011/12/111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf

The NHS Constitution:
http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

RPS Professional Standards for Homecare:
http://www.rpharms.com/unsecure-support-resources/professional-standards-for-homecare-services.asp

RPS Handbooks for Homecare Services:
http://www.rpharms.com/unsecure-support-resources/professional-standards-for-homecare-services.asp

Gain Share Framework and Guidance:
http://www.england.nhs.uk/wp-content/uploads/2014/01/princ-shar-benefits.pdf

System-wide Delivery of Medicines in Homecare (Department of Health Homecare Strategy Board):
http://www.rpharms.com/homecare-appendices/15b-homecare-technical-specification.docx

Technical System Specification: System-wide Delivery of Medicines in Homecare:
http://www.rpharms.com/homecare-appendices/15b-homecare-technical-specification.docx

Medicines Optimisation Clinical Reference Group:
http://www.england.nhs.uk/commissioning/spec-services/npc-crg/medicines-optimisation/

General Pharmaceutical Council Standards for Registered Pharmacies:
http://www.pharmacyregulation.org/standards/standards-registered-pharmacies

General Pharmaceutical Council Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, including on the internet:
http://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_on_distance_and_internet_services_.pdf

Annex 2 – EU Directive 2010/84 amending, as regards pharmacovigilance, Directive 2001/83/EC

*'**Article 116 A marketing authorisation may also be suspended, revoked or varied** where the particulars supporting the application as provided for in Articles 8, 10 or 11 are incorrect or have not been amended in accordance with Article 23, or **where any conditions referred to in Articles 21a**, 22 or 22a **have not been fulfilled** or where the controls referred to in Article 112 have not been carried out.'.*

*'**Article 21a** In addition to the provisions laid down in Article 19, a marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:*

(a) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;

(b) to conduct post-authorisation safety studies;

(c) to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Title IX;

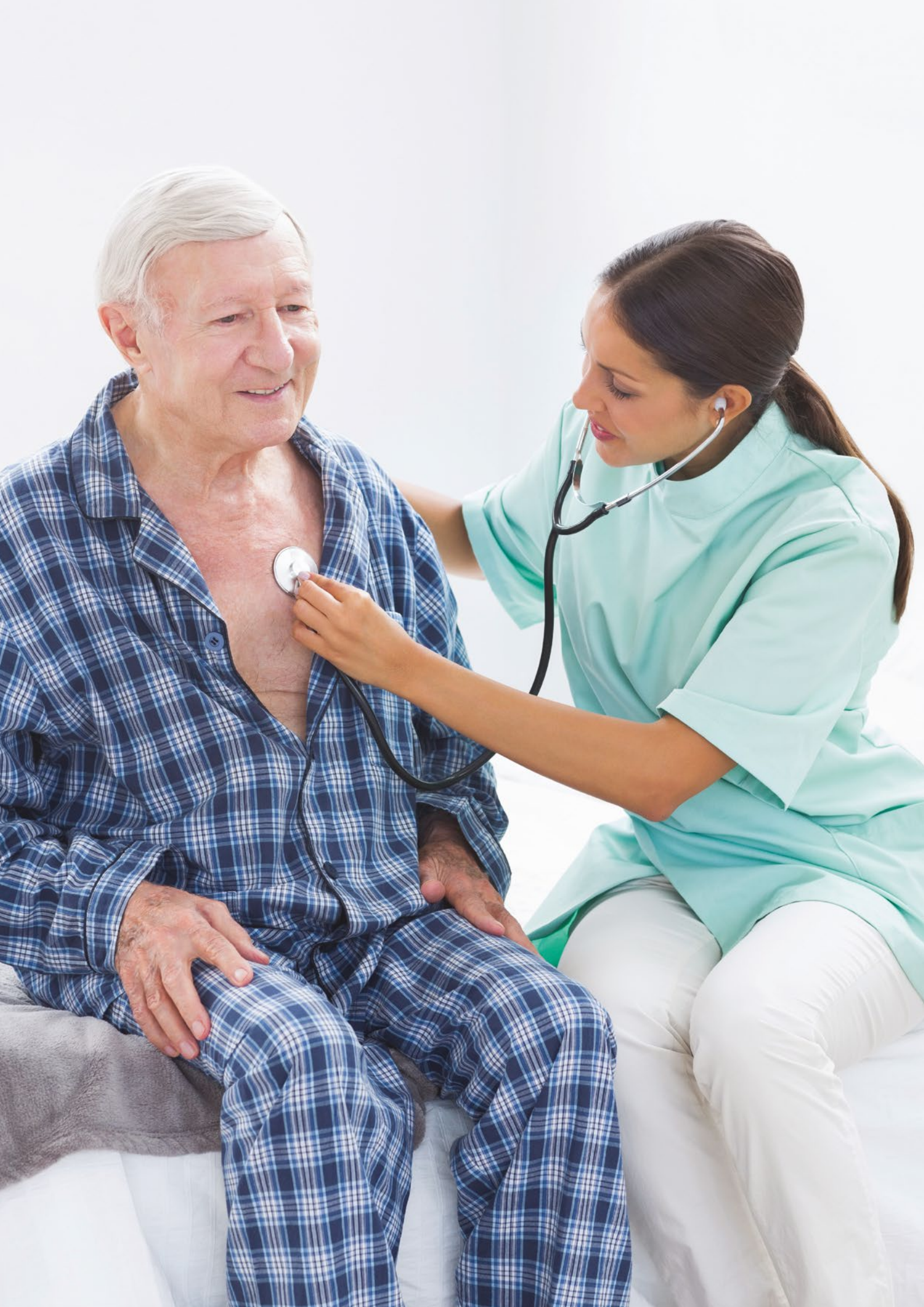
(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;

(e) the existence of an adequate pharmacovigilance system;

(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 22b while taking into account the scientific guidance referred to in Article 108a.

The marketing authorisation shall lay down deadlines for the fulfilment of these conditions where necessary.' .

Article 22a refers to similar conditions a competent authority may require after authorisation.



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WAL-0008-05/15