Delivering the Out-of-Hours Review

Securing Proper Access to Medicines in the Out-of-Hours Period

A PRACTICAL GUIDE for PCTs and Organised Providers
Gateway Number 4107
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Executive Summary

This guide is intended to support the implementation of recommendation 19 of the Report of the Independent Review of Out-of-Hours care Raising Standards for Patients. New Partnerships in Out-of-Hours Care\(^1\) which reads:

‘Other than in exceptional circumstances, patients should be able to receive the medication they need at the same time and in the same place as the out-of-hours consultation.’

Thirteen Action Points, summarised below, have been developed as a guide to implementation.

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**Action Point 1** Where patients’ clinical needs are such that treatment should start without delay, they should be able to access the medicines they need at the same time and the same place as the consultation. PCTs will therefore need to develop systems that will allow this to happen, ensuring that the responsibility for locating a pharmacist or source of medicine supply will no longer lie with the patient or their representative but with the out-of-hours provider.

**Action Point 2** Only by working collaboratively with all appropriate service providers will PCTs be able to secure services that deliver the medicines supply recommendations in the Out-of-Hours review.

**Action Point 3** Modernising access to medicines out-of-hours starts with a PCT stock-take of the existing local situation, paying particular attention to the realities of provision.

**Action Point 4** PCTs should develop a local formulary that includes all the medicines listed in the new national out-of-hours formulary. A ‘whole system’ approach should be adopted, including endorsement of the formulary by the appropriate local prescribing committee.

**Action Point 5** It is essential that every organised out-of-hours provider has robust, auditable systems in place to cover responsibility, reconciliation, record keeping and disposal requirements for the movement of drugs for which it is responsible.

**Action Point 6** PCTs will want to ensure that, where necessary and appropriate, patients are able to receive the benefit of the advice of a pharmacist (or dispensing doctor), although this need not necessarily be face to face.

**Action Point 7** PCTs will need to ensure that all health professionals are able to access appropriate levels of pharmaceutical advice out-of-hours.
Action Point 8  PCTs will want to consider and discuss fully, with all local stakeholders, how they can improve access to palliative care drugs in a way that best meets the needs of their community.

Action Point 9  As part of their stock-take, PCTs should specifically seek to improve the quality of service delivery for palliative care patients and their carers.

Action Point 10 For controlled drugs, a complete, documented and coherent audit trail should exist from stock room to patient. This should include drugs administered in the patient’s home and drugs returned for destruction.

Action Point 11 PCTs should implement new arrangements for the recording and reporting of medicines prescribed and supplied out-of-hours.

Action Point 12 PCTs need to ensure that mechanisms are in place for the collection of prescription charges and declaration of exemption status.

Action Point 13 By making appropriate local arrangements, PCTs will be able to improve the quality of their local data on actual community pharmacy opening hours and special out-of-hours schemes. This should include mechanisms for ensuring the information is kept up to date and available to NHS Direct.

The guidance will be supported by the Primary Care Trusts Supply of Medicines etc Out of Hours Directions 2005 (due to be published in April 2005) which will enable PCTs to contract, as they consider appropriate, with primary care providers for the provision of medicines Out-of-Hours.

The key points of this guidance are summarised in ‘Securing proper access to medicines in the out-of-hours period; Guidance for PCTs and Providers’ published by the Department of Health at http://www.out-of-hours.info
Section 1
Introduction


1.2 The Review proposed an integrated model of provision which was set out in the following diagram:

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1.3 Patients make a single call and, after prompt and careful assessment, they are either advised that their needs are such that they do not need an urgent, out-of-hours response, or they are given access to the service or professional best equipped to meeting their particular needs. Where patients’ needs can be properly and safely met on the telephone, this is achieved within a single call, regardless of the geographical location in which any individual service or professional is based; where patients need to be seen face-to-face, they end the telephone call with a clear understanding of when and where they will be seen. And if, for any reason, these arrangements change, the organised provider of out-of-hours services* calls the patient back and negotiates a new time with them. Thus, from the point of view of patients, the service is easy to use, prompt and effective, helping them to help themselves where appropriate, giving them access to the right kind of professional help where their needs require that help.³

1.4 In the context of this patient centred approach, the Review made two clear recommendations about the supply of medicines:

**Nineteen:** Other than in exceptional circumstances, patients should be able to receive the medication they need at the same time and in the same place as the out-of-hours consultation.

**Twenty:** The existing remuneration and contractual arrangements for out-of-hours providers and pharmaceutical services should be reviewed and where appropriate, modified to allow for the provision of all appropriate medicines in the manner set-out in Recommendation Nineteen.

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1.5 It also made clear that where patients needed to start their medication out-of-hours, they should be supplied with the full course – ‘starter packs’ (so widely used in the past) would no longer be acceptable.

1.6 The Review unambiguously re-stated the traditional definition of out-of-hours services. These services do not exist to meet routine medical needs but, rather are there to meet those urgent patient needs that cannot safely be deferred until the patient’s own GP practice is next open. It follows therefore, that only a small proportion of the total registered patient population will need access to those services (typically 10% in any one year) and only a small proportion of those patients will need immediate access to medicines.

1.7 All of this has three important implications for the supply of medicines out-of-hours:

- medicines need only be supplied during the out-of-hours period if delaying the onset of treatment would compromise clinical outcomes for the patient;

- where a course of treatment does need to be started without delay, PCTs will have to develop systems that allow full treatment courses to be supplied to patients at the same time as their consultation either by:
  - having a prescription dispensed by a nearby pharmacy;
  - or
  - an alternative mechanism of direct supply by another health professional if (because of the time of day) prompt access to pharmaceutical services is not possible;

- whatever arrangements are in place to deal with patients who need to start their medication without delay, the responsibility for locating a pharmacy or other source of supply should not lie with the patient or their representative but with the out-of-hours provider.

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Action Point 1

Where patients’ clinical needs are such that treatment should start without delay, they will need to be able to access the medicines they need at the ‘same time and the same place’* as the consultation. PCTs will therefore need to develop systems that will allow this to happen, ensuring that the responsibility for locating a pharmacy or source of medicine supply will no longer lie with the patient or their representative but with the out-of-hours provider.

1.8 This new approach to the supply of medicines out-of-hours is part of a wider programme of raising standards of care. As a result of the Carson Review, new national standards for organised providers of out-of-hours were introduced in 2002. From 1st January 2005 all those providing out-of-hours services (including GP practices that choose to provide out-of-hours services to their own patients), will have to comply with both the National Quality Requirements in the delivery of out-of-hours services and the Standards for Better Health that apply to all services provided to NHS patients. But, whilst the same standards will apply across the country, the manner in which they will be delivered will, of necessity, vary in each locality.

1.9 Exactly the same principles apply in the case of the supply of medicines – the provision of medicines across a large rural area, for example, will pose quite different challenges to those that exist in a small densely populated inner-city area. An identical, national model of medicines supply could never meet the individual needs or demands of every locality, be it urban, rural or a mixture of both. Primary Care Trusts (PCTs) are therefore to be given the

* Ideally, ‘same time same place’ means medicines are supplied as part of the out-of-hours consultation as for example with a One-Stop Primary Care Centre model, in which pharmacy services are co-located with primary care services throughout the out-of-hours period. In implementing this guidance, however, PCTs will have to be realistic and make the best possible use of existing available resources.

5 The original Out-of-Hours Quality Standards were published in June 2002; the National Quality Requirements in the Delivery of Out-of-Hours services were published in October 2004; both are available from http://www.out-of-hours.info/documents.php The Standards for Better Health are set out in National Standards Local Action, Health and Social Care Standards and Planning Framework 2005/6-2007/8, http://www.dh.gov.uk/publications
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responsibility to secure new out-of-hours medicines supply arrangements, as they alone are in a position to take full account both of the particular needs of their locality and of the range of existing services.

1.10 PCTs will only be able to discharge this responsibility effectively if they draw in the full range of service providers across the whole local health economy including: local pharmacists, NHS Walk-in Centres, Minor Injuries Units, NHS Direct and pharmacy services in secondary care, as well as other appropriate local organisations such as local GPs, GP Co-operatives, commercial and other out-of-hours providers, Local Pharmaceutical Committees, Hospital Trusts and Patient Forums. Working co-operatively and collaboratively with this wide variety of different individuals and organisations, PCTs will be able to develop an approach that will be able to deliver full implementation of Recommendation Nineteen.

**Action Point 2**

Only by working collaboratively with all appropriate service providers will PCTs be able to secure services that deliver the medicines supply recommendations in the Out-of-Hours review.

1.11 In developing their approach, PCTs should pay particular attention to the fact that the level of demand for out-of-hours services varies dramatically through the week and across the year. Indeed, demand is often at its highest (Sunday morning for example) at times when mainstream pharmacy provision is most difficult to access.

1.12 In common with the approach to out-of-hours services set-out in the guidance issued in November 2001, it makes sense for PCTs to start by taking stock of the existing situation, looking especially carefully at the realities of provision – existing data about out-of-hours pharmacy rotas, for example, can be very unreliable. The ownership and responsibility

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for data about pharmacies’ opening hours now lies with PCTs who provide this information to nhs.uk for inclusion in the national database. But this information is generally limited to contracted hours, and consequently does not reflect the true availability of pharmaceutical services within a given area.

1.13 Thus in carrying out this stock-take, it is critically important that PCTs work closely with all of those who currently deliver the service; existing organised providers in the area will invariably have good first-hand knowledge of the strengths and weaknesses of existing provision. Armed with this data, PCTs will then be in a position to deliver appropriate access to medicines out-of-hours.

**Action Point 3**

Modernising access to medicines out-of-hours starts with a PCT stock-take of the existing local situation, paying particular attention to the realities of provision.

1.14 From 1st April 2004, the new GMS contract introduced a major change in the way in which out-of-hours services are to be provided. When it is fully implemented, it will allow all GPs to transfer responsibility for out-of-hours services to PCTs. Even where GPs retain responsibility, PCTs will still have a critical role to play in ensuring that all their patients have access to high quality services in the out-of-hours period. PCTs will also have new powers to agree local contracts with organised providers and with GP practices.

1.15 While GPs may well continue to work in the out-of-hours period, it is likely that in many areas the traditional model of out-of-hours service in which the GPs themselves provided all the clinical services will disappear. In its place will come a new pattern of service provision, in which a wide variety of different health professionals, drawn from a variety of separate organisations will, together, deliver the most appropriate response to patients in the out-of-hours period. Such an approach is entirely consistent with the principles embodied in this Guide, where there is a
recurring emphasis on the need to draw on all the available services in a local health community to ensure that patients have prompt access to those medicines that they urgently need.

1.16 The remainder of this Guide explores in more detail the manner in which PCTs might most usefully tackle this task. Thus:

- **Section 2**
  summarises the basic requirements of a patient-centred medicines supply policy, including the new national out-of-hours formulary

- **Section 3**
  explores ways in which the appropriate supply of medicines might be organised

- **Section 4**
  explores specific issues in relation to palliative care and controlled drugs

- **Section 5**
  sets out the financial and reporting arrangements for out-of-hours medicines, including new ‘supply forms’

- **Section 6**
  describes the new ways in which NHS Direct will make direct referrals to pharmacy services.

- **Section 7**
  summarises PCTs’ responsibilities for implementing these new arrangements.
Section 2
Basic requirements of a patient-centred medicines supply policy

2.1 Prescribing in the out-of-hours situation is different from prescribing during the day. The out-of-hours professional is one of a number of people involved in a patient’s ongoing care, and it may be more appropriate if long-term decisions are taken after proper follow-up from those responsible for the patient’s in-hours clinical needs. Moreover, because there are few situations in which treatment needs to be started without delay, a limited formulary of drugs can be used in an out-of-hours situation without detriment to the health of the patient.

2.2 One of the basic principles of the Review was that wherever patients live, they should have access to a consistent level and standard of out-of-hours care, and part of the way of achieving this is to identify a minimum list of drugs which patients should be able to access from all organised providers. Working from the principles set out in Section 1, and drawing on the knowledge and experience of existing organised providers and up-to-date expert advice, an initial national formulary has been developed which is set out in Annex A.

2.3 The minimum list of drugs identified in this formulary is considered to be sufficient to be able to meet urgent patient needs in whichever geographical setting they are used. There is evidence that certain drugs on the list are more effective if started without delay (e.g. treatment for shingles, emergency hormonal contraception), whilst others provide immediate or early symptom relief (e.g. palliative care drugs).

2.4 It is recognised that some flexibility and local discretion is necessary in the choice of preparations for inclusion in this list. After discussion at an appropriate local prescribing committee PCTs and their local organised out-of-hours providers will therefore need to develop a local formulary of drugs that are deemed necessary for immediate use out-of-hours. As a minimum, this should include all the medicines that are listed in the national formulary, but it should also take into account local prescribing patterns, policies and guidelines and reflect a whole systems approach. PCTs therefore need to work together to develop out-
of-hours formularies which are consistent across the population covered by each out-of-hours provider.

2.5 Whilst all the drugs identified in the formulary should be available in every locality, this does not necessarily mean that every organised provider needs to carry the full range of drugs – local agreement may determine that certain drugs are only held by a particular provider within that local health community. Where this is the case, however, the PCT will need to ensure that this does not compromise patients’ prompt and easy access to these drugs. Following the approach set out in Section 1, all the drugs on this formulary should be available at the ‘same time and in the same place’ as the out-of-hours consultation.

**Action Point 4**

PCTs should develop a local formulary, endorsed by the appropriate local prescribing committee(s) which includes all the medicines listed in the new national out-of-hours formulary. A ‘whole system’ approach should be adopted, whereby neighbouring PCTs collaborate to develop out-of-hours formularies which are consistent across the population covered by each out-of-hours provider.

2.6 The local formulary should:
- include the items listed in the national formulary at Annex A
- be evidence based wherever possible
- be endorsed by an appropriate local prescribing committee
- be reviewed periodically
- be practical in use
- be consistent with expert advice
- act as a guideline to health care professionals prescribing out-of-hours
- be the reference for measuring the appropriateness of out-of-hours prescribing.
2.7 All medicines should be supplied in appropriate quantities for the condition being treated and comply with all relevant legislation regarding packaging, labelling and the use of patient information leaflets (PILs). 8, 9, 10, 11

2.8 Where medicines are supplied out-of-hours it should be a full course as appropriate to the presenting condition, i.e. the amount that would otherwise have been prescribed. The supply of starter packs is not appropriate.

2.9 Manufacturers’ original packs should be used wherever possible. Any pre-packed items should only be obtained from a fully licensed provider who complies with the relevant legislation. Each individual organisation should have a full audit trail to track movements of drugs identifying the prescriber (or supplier) at the point of issue.

8 Guidelines for the safe and secure handling of Medicines – Duthie Report – Department of Health 1988

9 Medicines Management (Safe and secure handling of medicines), Controls Assurance Statement, Department of Health, 2003 – available at: http://www.info.doh.gov.uk/doh/rm5.nsf/e38b211034b364b500256735003e21ae/824f30c511a06e8900256b1b005f9216?OpenDocument


2.10 The existence of a national formulary of out-of-hours medicines creates new opportunities in the supply and preparation of these core medicines. In order to maximise potential economies of scale and value for money, PCTs should explore the possibility of collaborating in the purchase and preparation of out-of-hours medicines.

2.11 Where appropriate, certain items on the formulary can be made available for supply by other primary or secondary health care professionals working to approved Patient Group Directions (PGDs). Further guidance and information on template PGDs can be found on the website: http://www.groupprotocols.org.uk/

2.12 See also specific sections on palliative care and controlled drugs in Section 4 below.

**Action Point 5**

It is essential that every organised provider has robust, auditable systems in place to cover responsibility, reconciliation, record keeping and disposal requirements for the drugs for which it is responsible.
Section 3

Organisation of medicines supply services out-of-hours

3.1 The normal means for providing patients with medicines as part of NHS services in the community will remain a prescription issued by a prescriber and dispensed during normal opening hours by a community pharmacist as part of pharmaceutical services or Local Pharmaceutical Services (LPS), or (in rural areas) a dispensing doctor.* This will apply whether the patient consults primary care services during normal hours or out-of-hours.

3.2 However,

■ where patients present out-of-hours with a condition which, in the clinical judgement of the prescriber, calls for a course of medicine that should be started without delay;

and

■ because of the time of day or week, those patients are unlikely to be able to access a pharmacy (or their dispensing doctor) and would therefore experience a significant delay to the start of treatment which would compromise the clinical outcome,

then alternative arrangements should be in place for the supply of the appropriate medicines, where it is safe so to do.

3.3 Giving patients direct, immediate access to a pharmacy (or a doctor’s dispensary) at, or close to the place at which they consult out-of-hours services, represents perhaps the simplest way of making these arrangements.

3.4 In practice, however, it will often not be cost effective for pharmacies to remain open for long periods out-of-hours (or for PCTs to pay them to do so), unless the volume of business is

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12 Local Pharmaceutical Services Guidance Notes available on the website address:
http://www.dh.gov.uk/assetRoot/04/06/70/63/04067063.pdf

* Dispensing doctors are able to supply medicines to their own patients. If they have chosen not to transfer responsibility for providing out-of-hours services they will need to make provision to be able to supply out-of-hours formulary medicines to these patients in the same way as they do in-hours. All the references to dispensing doctors in this guide should be read in the same way.
sufficient to justify such opening. Alternative arrangements will therefore, need to be made for those times and places where it would be uneconomic to open a pharmacy.

3.5 Whatever arrangements are in place to deal with patients who need to start their medication without delay, the responsibility for locating a pharmacy or source of medicine supply should not lie with the patient or their representative but with the out-of-hours provider.

3.6 Where such alternative arrangements are used patients should, where appropriate, be able to receive the benefit of the advice of a pharmacist (or dispensing doctor). This need not necessarily be a ‘face to face’ contact, and NHS Direct is currently exploring whether such a service could be provided nationally.

3.7 It is recognised that there will always be circumstances where it is necessary to call out a pharmacist, and systems must be in place to deal with these very rare cases. Attempts should be made, however, to anticipate the most frequently encountered needs, including those for palliative care for, in this way, it will be possible to minimise the need for recourse to such special measures.

3.8 Where medicines are supplied out-of-hours it should be a full course as appropriate to the presenting condition, i.e. the amount that would otherwise have been prescribed. The supply of starter packs is not appropriate.

**Action Point 6**

PCTs should ensure that, where necessary and appropriate, patients are able to receive the benefit of the advice of a pharmacist or dispensing doctor, although this need not necessarily be face to face.
Making best use of all service providers in the local health community

3.9 It is important to remember that primary care centres operated by organised out-of-hours providers may be just one of a number of possible locations for access to medicines out-of-hours. NHS walk-in centres, minor injuries units or local hospitals are just some examples of possible alternative locations. Thus, PCTs will need to take proper account of all the resources at their disposal. Ending unnecessary overlap in provision represents one important way of making the best possible use of existing resources.

3.10 Some suggestions for out-of-hours arrangements are listed below. This list is by no means exhaustive and seeks only to illustrate possible arrangements. The intention would be for any special arrangements for the supply of the specified formulary items to be operational only for the duration of the out-of-hours period (i.e. at times when full GP and community pharmacy services are not widely available). Services would then revert to existing arrangements during normal hours.

3.11 In determining these local arrangements, PCTs should always take account of the principle at the heart of the original Review, namely to design the service in such a way that it best meets the needs of the patients it is designed to serve. Such an approach may require some additional local investment, but significant progress can often also be achieved through service re-design and modernisation including, in particular, the improved use of existing resources.

3.12 Options include:

- use of local resources, such as existing extended hours pharmacies and NHS walk-in centres, either at or in the near vicinity of the out-of-hours primary care centre;

- specifically funded out-of-hours opening by existing local pharmacies, either at or in the near vicinity of the out-of-hours primary care centre, taking advantage of the flexibilities created by the new pharmacy contract;

- a new pharmacy within the out-of-hours primary care centre, either to provide a general service or one restricted to out-of-hours. Pharmacies that are part of consortia developing...
new one-stop primary care centres will be one of four models exempt completely from control of entry regulatory tests. (See 3.13 below) 

- a new pharmacy within the out-of-hours primary care centre operating under a Local Pharmaceutical Services (LPS) pilot scheme. These pilot schemes require a formal application for approval by the Secretary of State, but pharmacies operating within such a pilot are outside the normal control of entry rules. Out-of-hours medicines supply is a good example of a PCT defined need that could be met using an LPS contract – see the Department of Health’s guidance notes on LPS; 

- a stock of pre-packed items held in the out-of-hours primary care centre. Supplies must comply with all relevant legislation and should be supported by a comprehensive service level agreement to provide a pharmaceutical ‘top up’ service. Pre-packed items should provide a full course of treatment;

- the delivery of medication, if appropriate, to the patient’s home from an approved pharmacy;

- the use of local hospital pharmacy departments, for supply or access to on-call rotas.

A new electronic guide, ‘Providing Medicines Out-of-Hours: Achieving Safe Practice’ will be made available before the end of the year. It has been designed to help PCTs and providers of out-of-hours services understand the relevant medicines legislation and thus enable them to achieve safe and legal practice. This has been produced jointly by the National Pharmaceutical Association (NPA), the Pharmaceutical Services Negotiating Committee (PSNC), the Royal Pharmaceutical Society (RPSGB), the Company Chemists’ Association (CCA) and the Department of Health. It will be available at http://www.npa.co.uk

3.13 The Government’s response to the OFT Report on Control of entry regulations and retail pharmacy services in the UK proposes the introduction of new criteria of ‘competition and choice’ to the current regulatory test for pharmacy applications. In addition, four types of

13 http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/fs/en

pharmacy application will be exempt from that test: those in out of town shopping developments over 15,000 square metres; those intending to open for more than 100 hours per week; those which are wholly internet or mail order based; and those that are part of a consortium developing new one-stop primary care centres. This should have the result of widening access to pharmaceutical services out-of-hours, including the supply of over the counter medicines and availability of advice from a pharmacist.

3.14 While some of these approaches set out in 3.12 above may seem ambitious, examples of innovative schemes and existing good practice will be accessible through the Department of Health’s out-of-hours website at http://www.out-of-hours.info

3.15 PCTs and organised out-of-hours providers should also ensure that health professionals have the means of obtaining appropriate pharmaceutical advice in out-of-hours situations. Specific advice from Macmillan nurses and palliative care specialists has also been shown to be particularly valuable. This advice could be either directly on site, via the telephone or via NHS Direct. Where these do not exist, PCTs should seek to develop sources of expertise in palliative care and medicines as part of their palliative care and medicines management strategies.

Action Point 7
PCTs will need to ensure that all Health Professionals are able to access appropriate levels of pharmaceutical advice out-of-hours.

15 http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/fs/en
Possible scenarios for the supply of medicines from the agreed
Out-of-Hours formulary

3.16 The range of different approaches described above, can be further illustrated by the following
different scenarios in which patients would achieve prompt access to the medicines that they
need in the out-of-hours period:

- PCTs negotiate with pharmacies and out-of-hours providers to agree and co-ordinate best
  opening times at weekend and bank holidays to meet expected demand.

- patient seen by NHS walk-in centre (WiC) nurse. Computer
  aided decision support software is used to help the nurse
decide on the most appropriate treatment following their
diagnosis. The nurse makes a supply (via PGD) from the
NHS WiC stock of pre-packed formulary drugs;

- patient is seen at a primary care centre by health care
  professional with prescribing rights. Treatment without delay
  is appropriate. If there is either an attached pharmacy or
  pharmacy in the very near vicinity, then supply can be via
  prescription;

- patient seen at Primary Care Centre by health care
  professional. Treatment without delay is appropriate, but
  pharmacy services are not available. Medication is issued from pre-packed stock;

- health care professional sees patient at home. Treatment without delay is appropriate. Health
  care professional supplies medication from pre-packed stock carried in car;

- patient seen at home by health care professional. Delivery of medication from pre-packed
  stock or from pharmacy arranged.

- patient who does not need to see a health care professional, but is medically unfit to travel.
  Delivery of medication arranged or advised to seek advice the next working day.
‘Doctor’s Bags’ in the Out-of-Hours Period

3.17 A very small number of doctors continue to provide their own, personal service in the out-of-hours period, and would therefore use their own bag in exactly the same way as they do in-hours. The majority of doctors, however, delegate responsibility for the provision of their service in the out-of-hours period to an accredited organised provider and, until the end of 2004, this will remain the position for GPs who have not transferred responsibility for out-of-hours services to a PCT. From January 2005 or earlier where GP contractors agree, PCTs will be able to take over responsibility for out-of-hours services completely, making alternative arrangements, typically by contracting directly with organised out-of-hours providers or by providing services themselves.

3.18 The Requirements and Standards applicable to out-of-hours services require organised providers (including PCTs) to put mechanisms in place to purchase, store and supply drugs in accordance with current regulations, licensing requirements and best practice and this clearly has implications for the use that out-of-hours providers make of ‘doctor’s bags’. In order to be able to comply with this, we anticipate the model that many providers will choose to adopt will be to take responsibility for equipping, stocking, monitoring and auditing of medicines used from the ‘doctor’s bag’. In practice therefore, the ‘doctor’s bag’ will become the ‘provider’s bag’.

3.19 Therefore, where a health professional visits a patient on behalf of the organised out-of-hours provider, s/he will have access to the provider’s bag from which any required medicines will be supplied. Where providers do choose to follow this approach, they will obviously need to develop their own robust audit trails for all items issued from the bag, writing prescriptions for other required medicines as appropriate. In the case of CDs, separate, additional procedures will be required to ensure that the provider’s records for the administration of controlled drugs are properly maintained and updated.

Section 4

Access to palliative care drugs and controlled drugs out-of-hours

4.1 It is clear that there are special problems in respect of the supply of medicines to palliative care patients in the community out-of-hours. There is inequity of access and widespread difficulty in accessing a full range of palliative care drugs out-of-hours, often resulting in delays in symptom control. And yet, if provision were better (at both a strategic and operational level), there would be real improvements in the quality of life of both patients and those who care for them and, as a result, there may well be fewer unnecessary hospital admissions.

4.2 The condition of palliative care patients can deteriorate or change rapidly. Many of these crises occur during the out-of-hours period and require urgent treatment and drug intervention. It is therefore important that all healthcare professionals have appropriate access to drugs (including controlled drugs) and a good understanding of which drug to use and how to prescribe them to best effect.

4.3 PCTs will therefore want to carry out a ‘stock-take’ of their current situation in respect of access to palliative care drugs and consider how best to achieve the recommendations of the Carson Review. The primary objective is to ensure better and more appropriate patient (and carer) access to palliative care drugs, and in particular those listed in the national formulary (see Annex A),

4.4 The three underlying principles to this process should be:

- the need to take a sensible and realistic approach to potential service delivery solutions and ensure that the service is re-designed around the needs of the patient;
- the need to ensure that the solutions maximise safety and actually work in practice;
- the need to ensure that the specific legal and good practice requirements relating to the effective management of controlled drugs are fully considered during implementation.
4.5 However, in addition, particular attention should be paid to ensuring that the service also achieves the following standards:

- appropriate advice, information and support from health professionals who are well informed about the patient’s condition, medication and future management;
- good anticipatory care and proactive planning by the primary health care team;
- high quality symptom control;
- availability of appropriate drugs (or equipment) in the home. This is especially important if it is not appropriate for the carer to leave the patient;
- safety for patients, their carers and relatives, the public and for healthcare professionals;
- efficient transfer of information to and from those working during the day and those working out-of-hours. This should normally occur during the next working day. Examples of effective transfer mechanisms include a handover form, patient held records or electronic records. For examples of good practice see http://www.out-of-hours.info/

**Action Point 8**

PCTs will want to consider and discuss fully, with all local stakeholders, how they can improve access to palliative care drugs in a way that best meets the needs of their community.

4.6 Anticipating the patient’s needs, including possible changes in dosage or drugs required, is essential. Deteriorating patients may need certain drugs not previously used.

4.7 Following local discussion, PCTs should develop an approach that meets the needs of their particular area. Some suggestions are outlined below, it may well be that a combination of these solutions may be required to cover the whole out-of-hours period:

- GPs or health care professionals proactively encouraged to prescribe sufficient drugs to be kept at the patient’s home to take account of possible changes in the patient’s condition
during the out-of-hours periods (including Bank Holidays), and thus allow on-call health care professionals to administer these drugs as and when they are required. Such an approach would need to be carefully balanced with the risk to safety of increased quantities of drugs (particularly controlled drugs) left in the patient’s home;

- drugs prescribed on an ‘as required’ basis and left in the patient’s home for nurse administration. This should be in accordance with local protocols. Suggestions of possible drugs to leave in the home are detailed in Annex A. Note: a range of additional regulatory and good practice issues must be considered in relation to controlled drugs;

- drugs supplied at the time of consultation. Note: a range of additional regulatory and good practice issues must be considered in relation to controlled drugs;

- use of sealed palliative care treatment packs that contain a locally determined range of symptom control drugs (but not controlled drugs). See Annex A for suggested contents. These packs can be left in the patient’s home, provided each item in the pack is prescribed for that patient on an ‘as required’ basis. As it would not be appropriate to include controlled drugs in such a pack, special, separate arrangements for these drugs must be made in accordance with the relevant legislation and regulations (summarised in the Controlled Drugs section below). However, the PCT will need to ensure that these arrangements do not compromise patients’ prompt and easy access to these drugs;

- use of existing specific palliative care or out-of-hours pharmacy schemes if appropriate.

**Action Point 9**

As part of their stock-take, PCTs should seek to improve the quality of service delivery for palliative care patients and their carers by setting up systems that will ensure that they have prompt and easy access to medicines in the out-of-hours period.
If sealed palliative care treatment packs are to be used, then it is important that a complete audit trail exists from stockroom to patient and, in addition, that local protocols are developed to cover the issues listed below:

- contents of box
- protocol, procedures for supply and disposal
- storage requirements
- professionals authorised to collect, supply or use
- record keeping and recording
- transport
- administration
- security

It is essential that risks to the family, visitors, patients and other personnel are fully assessed – systems should be in place to identify what might go wrong including how to prevent it happening or to minimise the impact.
Controlled Drugs

4.9 The use and management of controlled drugs is governed by additional legislation compared to other drugs. It is expected that the management of controlled drugs will be refined and strengthened in light of the Shipman case and any recommendations made by the Public Enquiry set up to investigate it.\textsuperscript{17}

4.10 Accordingly, wherever the provision of controlled drugs is required out-of-hours, both commissioners and providers of the relevant services locally must take full account of current legal / regulatory frameworks (including the Misuse of Drugs Act and Misuse of Drugs Regulations), plus nationally recognised good practice guidance.

4.11 To assist local service commissioners and providers in this process, a comprehensive, Department of Health commissioned support document, entitled \textit{A guide to good practice in the management of controlled drugs in primary care (England)}, will be made widely available to the NHS.\textsuperscript{18}

4.12 Some of the key principles that must be addressed, when considering the provision and use of any controlled drugs in an out-of-hours situation, include:

- doctors and pharmacists are legally permitted to possess and supply controlled drugs when acting in their capacity as such. As long as the ordering and handling of such drugs in an organised provider is undertaken by a doctor or a pharmacist, no licence is necessary. However, if these duties are to be undertaken by anyone else (e.g. an office manager), an organised provider (including a PCT) requires a Home Office licence;\textsuperscript{19}

- each provider should keep a ‘central’ register for all controlled drugs;

\textsuperscript{17} Further information on how to obtain codes will be issued by the PPA: http://www.the-shipman-inquiry.org.uk/fourthreport.asp

\textsuperscript{18} A guide to good practice in the management of controlled drugs in primary care (England) is currently available in preview form from the National Prescribing Centre at http://www.npc.co.uk/

\textsuperscript{19} For information on how to apply for a Home Office licence see http://www.homeoffice.gov.uk/drugs/licensing/index.html
a complete documented and coherent audit trail should also exist – from requisition to stock room, prescription to patient location, administration and/or destruction, where relevant;

a formal system needs to be put in place for patients’ controlled drugs, which are no longer required. The issues surrounding this are the subject of further work and development by the Department of Health and further information will be made available in due course;

full and robust clinical records should be kept. They should make clear the date, time of administration, strength, presentation, form, batch number and expiry date of any drugs involved;

controlled drugs should be stored within a locked cabinet, complying with the relevant legislation, in the out-of-hours primary care centre. Procedures allowing access to the controlled drugs stock should always ensure it is carried out in the presence of two of the following types of individual: a doctor or pharmacist and a designated out-of-hours supervisor, each with appropriate identification;

a lead clinician, ideally a pharmacist, should be nominated to monitor, audit and reconcile the use of any controlled drugs and the relevant register;

all clinical practitioners involved in local schemes should have access to national/local guidance, plus local training on statutory requirements and good practice in the use of controlled drugs, particularly in primary care.

**Action Point 10**

For controlled drugs, a complete, documented and coherent audit trail should exist from stock room to patient. This should include drugs administered in the patients’ home and drugs returned for destruction.
Section 5
Financial and reporting arrangements

5.1 Over the last decade, there has been a dramatic change in the way in which out-of-hours care has been provided. When health care professionals were providing personal cover for their own patients, it made sense for the cost of the medicines they prescribed to be allocated to that health care professional. Today, however, organised providers provide most out-of-hours cover, and it is therefore appropriate to re-examine the way in which these costs are attributed.

5.2 Under current arrangements, there are several mechanisms for attributing drug costs:

- some health care professionals use their own prescription pads and all drug costs are attributed to them. This can cause problems with the drug budget of health care professionals who work frequently for the organisation.

- some organised out-of-hours providers use the prescribing code of each patient’s own GP. This is often logistically difficult, both for out-of-hours providers and the Prescription Pricing Authority (PPA) resulting in significant volumes of prescriptions with ‘unidentified health care professionals’.

- other organised out-of-hours providers have been given their own prescribing code, but in only a few cases has a prescribing budget been agreed.

5.3 The lack of a single uniform system means that monitoring or collection of meaningful out-of-hours prescribing data is impossible. This lack of data poses serious problems for the effective clinical governance of the service as well as making effective demand management and capacity planning very difficult.
New proposals for the data capture and reporting of all Out-of-Hours supplied medicines

5.4 It is proposed that the cost of all medicines supplied following an out-of-hours consultation with an organised provider be charged against the prescribing section of the relevant PCT’s unified budget, regardless of the way in which those medicines are supplied.

5.5 This will mean that FP10 prescribing will continue as now, with an FP10 prescription form being completed by the prescriber and submitted to a pharmacist for dispensing by the patient or patient representative. However, in future PCTs should arrange for the FP10 to carry a new, unique out-of-hours identification code identifying the organised provider for whom the prescriber is working.

5.6 In addition, where PCTs make arrangements with out-of-hours providers for medicines to be supplied directly to patients, there will be a new supply form (FP10PREC) in order to record supplies made directly to a patient. These new forms will be submitted to the PPA for data capture. This will mean that PPA will be able to supply monthly reports to PCTs and organised providers on medicines supplied out-of-hours.
Forms to be used

5.7 PCTs (or their prescription form purchasing & distribution unit/agency) will need to supply two different types of prescription form to their out-of-hours providers (both obtainable from Astron in the normal way). These are:

- standard FP10 prescription forms which will be dispensed by a community pharmacy – either computer type FP10SS or FP10NC for hand written prescriptions or FP10P (PN version) for any qualified nurse prescribers they directly employ. Three GP software supplier systems are currently accredited to overprint nurse prescription form details using FP10SS (ref http://www.nhsia.nhs.uk/sat/testing/pages/temp.asp). Therefore qualified nurse prescribers directly employed by the out-of-hours provider would use either computer type FP10SS or FP10P (PN version) for hand written prescriptions and

- new supply forms – FP10PREC – which will be used to record items supplied direct to a patient (that is, any item not dispensed through a community pharmacy but given directly to a patient).

5.8 PCTs may also permit blank FP10SS forms to be used by out-of-hours providers to produce supply forms, provided they are satisfied that the providers have the appropriate software to over-print the necessary annotations to identify the form as a FP10PREC. Currently the accreditation of blank prescription form printing is undertaken by the NHSIA System Accreditation and Testing (SAT) Programme (http://www.nhsia.nhs.uk/sat/pages/default.asp). This centralised process ensures that each GP systems supplier complies with the relevant regulations and overprinting specifications.

5.9 When dispensed, prescription forms issued on behalf of out-of-hours providers will be submitted to the PPA by pharmacies in the normal way for reimbursement. In addition, PCTs should arrange for out-of-hours providers to submit all FP10PRECs, on a monthly basis, to the PPA for information gathering purposes but not reimbursement. PCTs and out-of-hours providers may wish to use this information for cost reconciliation and audit purposes.

5.10 Dispensing doctors will continue, as now, to record the items they dispense on FP10s.

20 Non FP 10 supply forms overprint specification available at http://www.ppa.org.uk/ppa/prescform_overspec.htm
Reporting

5.11 As from January 2005 the Prescription Pricing Authority (PPA) will:

- allocate a unique identifying code to each out-of-hours provider. This will enable the PPA to separately capture, process and report on all medicines prescribed by out-of-hours providers in the same way as currently for GP practices;

- collect data on drugs and appliances supplied directly to patients. This data will be collected and submitted to the PPA using the newly developed FP10PRE. Electronic transfer will be developed in the future.

- provide monthly out-of-hours expenditure and activity data, initially to providers and their parent PCT(s), for items prescribed and supplied by out-of-hours providers. Both reports will use the Drug Tariff net ingredient cost. This is not intended to reflect the actual drug cost, which may very locally, but rather to provide indicative, comparable drug costs for monitoring purposes.

5.12 Using the above mechanism, out-of-hours providers will be treated in the same way as a health care professional or practice within the PCT and as such will be included in prescribing monitoring processes. Each out-of-hours provider will need to identify a clinician who will co-ordinate and lead on prescribing issues. Where providers cover more than one PCT area it is particularly important that providers have mechanisms to be able manage multiple prescription pads which each uniquely identify the parent PCT. This will ensure organisations are able to fully monitor out-of-hours prescribing and supply and avoid the logistical problems outlined in 5.2.

5.13 PCTs will be expected to make appropriate local arrangements for these out-of-hours costs to be attributed to and managed as part of the appropriate primary care prescribing budget.

5.14 Reports will be provided to the PCT which requests the code for the organised provider. Where a provider contracts with more than one PCT, PCTs should agree between them which
is to act as the provider’s parent PCT. An organised provider may have more than one code (and therefore more than one parent PCT) but, if so, it will be for the provider and the PCT concerned to agree how to ensure that the correct code is used on prescription and supply forms. Where a provider has more than one code, the PPA will provide separate reports for each code (but will not be able to provide a composite report for the provider as a whole.)

5.15 Further more detailed information on how to apply for a code, order prescriptions etc., will be issued in due course by the PPA.

**Action Point 11**

PCTs should implement new arrangements for the recording and reporting of medicines prescribed and supplied out-of-hours.
Costs

5.16 New arrangements for out-of-hours access should not, by themselves, have a significant effect on expenditure on medicines. The source of funding for any other related developments will depend on the nature of the development in question. For example, funding for additional pharmacy opening might be a call on the PCT’s unified budgets, whereas other costs might be a legitimate call on the out-of-hours development fund.

5.17 Once the service models are in place, it is essential that links are established and maintained with the overall PCT planning and local development plan (LDP) processes. PCTs should ensure continued funding is available to support the delivery of recommendation nineteen of the out-of-hours review (see Section 1).
Prescription Charges

5.18 Arrangements will need to be made for prescription charges. The NHS (Charges for Drugs and Appliances) Regulations 2000 will be amended so as to require the collection of a prescription charge when medicines are supplied out-of-hours as part of primary medical services, just as at any other time, regardless of whether a prescription form is used, unless the patient is exempt and completes a declaration to this effect. Other patients will be required to complete a declaration to say how much they have paid. (The NHS Counter Fraud and Security Management Service will be able to provide further guidance\textsuperscript{21}). The only exceptions are:

- contraceptives
- items supplied for ‘immediate treatment’ where no order is made on a prescription form
- items personally administered

5.19 Where PCTs make arrangements for out-of-hours providers to supply medicines directly to patients, they will need to ensure that appropriate arrangements are in place in relation to prescription charges. Patients’ exemption status should always be checked and a patient signature obtained. Charges should be collected as appropriate.

\textsuperscript{21} The NHS Counter Fraud and Security Management Service at: http://www.cfsms.nhs.uk/
5.20 If charges cannot be collected (for whatever reason) at the point of consultation, then an invoice can either be left with the patient or posted at a later date. Some out-of-hours computer software systems may offer a solution to this particular problem. PCTs and providers need to agree:

- local payment systems which minimise opportunities for fraud;
- appropriate debt recovery mechanisms for prescription charges (using existing systems and methods wherever possible).

5.21 Working closely with the appropriate PCT, the out-of-hours provider will need to develop its own procedures for the collection of payments.

**Action Point 12**

PCTs need to ensure that mechanisms are in place for the collection of prescription charges and declaration of exemption status.
Section 6
Pharmacy referrals from NHS Direct

6.1 As outlined in the NHS Plan, all NHS Direct sites now have formal mechanisms in place to refer callers to a community pharmacy. NHS Direct sites will also have agreements with local pharmacy organisations to provide training and communications on pharmacy issues.

6.2 Callers to NHS Direct will be referred to a community pharmacist for a range of minor ailments, the criteria for which are:

- a pharmacy only medicine (‘P’) would be first line treatment;
- the condition is only routinely dealt with by a pharmacist or advice from a pharmacist will have added value to the treatment;
- there is no clinical risk associated with a pharmacy referral.

6.3 Although minor, there will be many conditions where the discomfort caused may encourage the caller to seek advice and treatment as soon as possible. NHS Direct nurses will have greater confidence in referring callers to pharmacy services out-of-hours where they can be certain that the patient would be able easily to access the service.

6.4 As the role of the pharmacist changes over the coming years with developments such as repeat prescribing management, pharmacist prescribing, supplementary prescribing and medicines management, the number of referrals to community pharmacy is likely to increase further.

6.5 Appropriate access to pharmacy services could therefore temper the demands placed on other services, and PCTs should therefore give consideration to the full utilisation of pharmacy services to help meet the demands of the local health economy. The proposed changes to the control of entry requirements for NHS pharmaceutical services, in particular the exemption for pharmacies which intend to open more than 100 hours per week, should widen access to pharmaceutical services out-of-hours, including the supply of over the counter medicines and availability of advice from a pharmacist. See also section 3.12 and 3.13.
Local Pharmacy Information

6.6 In order for NHS Direct to be able to provide quick and accurate information to callers on the availability of local pharmacy services out-of-hours, it needs to have access to a comprehensive and accurate database. It is essential that this database includes information on actual opening times and specialist services e.g. palliative care. Ideally, it should also provide a postcode search facility so that callers may be directed to the nearest pharmacy providing the required service. This is particularly important within the context of the virtual contact centre setting, where the NHS Direct adviser may not otherwise be aware of the character of provision in a particular locality. NHS Direct will also need to know how to advise patients receiving oxygen at home in the event that they have problems such as an equipment breakdown out-of-hours.

6.7 The ownership and responsibility for contractual data lies with PCTs. The data is currently collected and maintained by PCT web editors, who provide this information to nhs.uk for inclusion in the national database. The information is generally limited to contracted hours and consequently often does not reflect the true availability of pharmaceutical services within a given area. The need for up to date, accurate service availability information is acute for out-of-hours periods, but particularly for Bank Holidays.
PCTs should therefore make local arrangements to improve the quality of their local community pharmacy data, particularly actual opening hours and special out-of-hours schemes, and they must ensure that the data is kept up-to-date. Options to consider are:

- PCT commissions NHS Direct to take on web editor functionality and so collect, validate and maintain data on its behalf.\(^\text{22}\)
- PCT collects data and seeks validation from the Local Pharmaceutical Committee.
- PCT sub-contracts with Local Pharmaceutical Committee to collect all data, and provide it to the PCT web editors.

**Action Point 13**

By making appropriate local arrangements, PCTs will be able to improve the quality of their local data on actual community pharmacy opening hours and special out-of-hours schemes. This should include mechanisms for ensuring the information is kept up to date and available to NHS Direct.

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Section 7
Implementing the new arrangements

7.1 Medicines supply is a key element in out-of-hours services - indeed, for many patients this is the most visible part of the process. Not least for this reason therefore, the national Quality Standards for out-of-hours primary medical services specify that medicines should be purchased, stored, supplied, administered and disposed of in a safe and secure manner in accordance with current legislation, licensing requirements and best practice, and organised providers are also required to make proper provision for the equipment they use and the premises in which that equipment is used.

7.2 In the past, the accreditation of organised providers has been the means of securing compliance with these Standards. In future compliance will be secured through the contract that PCTs enter into with organised providers of out-of-hours services (or by PCTs providing the service themselves.) Thus, as PCTs take over responsibility for out-of-hours services they need to ensure that the new service is also capable of meeting all the national standards that apply to out-of-hours services, including the new national Quality Requirements (see paragraph 1.8 above).

7.3 As set out in Section 1, the first step for most PCTs will be to take stock of the existing arrangements for out-of-hours access to medicines in their area.

7.4 Supply of medicines via a pharmacy (or dispensing doctor) remains the preferred approach even during the out-of-hours period, and in implementing this guidance, PCTs will be able to use their existing powers to support community pharmacies to stay open longer, or to provide other services (e.g. on-call arrangements).

7.5 But where this is not practical, PCTs may need to contract directly with providers of out of hours services to supply medicines or appliances and/or provide them themselves as part of PCT-led (PCTMS) out of hours services.
In April 2005 Directions will be issued which will enable PCTs to make arrangements as they consider appropriate for providers of out of hours primary medical services to supply medicines and appliances to patients using out of hours services who cannot reasonably be expected to wait until core hours to obtain them. At the same time the GMS Contract Regulations and PMS Agreement Regulations will be amended to enable PCTs to contract, on the same terms as with other providers of out-of-hours services, for the supply of medicines and appliances out-of-hours with those GMS and PMS contractors that retain responsibility for out-of-hours services.

It is for PCTs to decide what arrangements are necessary or desirable to make, but before making such arrangements, PCTs must consider the effect on existing pharmaceutical services, and must keep the arrangements under review. Any arrangements PCTs make would be in addition to the existing obligation on all providers of primary medical services to supply medicines and appliances that are needed for the immediate treatment of a patient before such provision can be otherwise obtained.\(^{23}\)

Where PCTs make such arrangements, contractors will be required to ensure that a record is made on a ‘supply form’ (see Section 3) and that evidence is sought of patients’ claims to exemption from prescription charges.

PCTs can make arrangements with providers of out-of-hours services whether or not the PCT is itself directly commissioning the out-of-hours service. In other words, where GP practices have decided (for whatever reason) to retain responsibility for out-of-hours services, but then sub-contract that responsibility to (say) a GP co-operative, PCTs will be free, if they wish, to make arrangements with that co-operative to supply medicines out-of-hours.

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\(^{23}\) See, for example, paragraph 52 of Schedule 5 of the PMS Agreement Regulations. Equivalent rules apply to GMS, APMS and PCTMS.
Acknowledgements and members of the medicines supply sub-group

May I take this opportunity to thank all of those who have worked so hard to complete this piece of work, Dr. Nicholas Reeves (Out-of-Hours Implementation Team), Dr. Alex Yeates (GP and Medical Director to Adastra Software Ltd and Meddoc), Joe Asghar (Regional Pharmaceutical Adviser – NHS Northern & Yorkshire), Dr. Helen Metcalf (GP and Secretary to NAGPC), Ash Pandya (National Pharmacy Project Manager – NHS Direct), Bruce Warner (Community/Hospital and PCT Pharmacist – Sheffield), Debbie Allison (Healthcall), Karen Hatch (NHS North West), Richard Rook (Department of Health), Peter Dunlevy (Department of Health).

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Annex A

National Out-of-Hours Formulary

A1 The following National Out-of-Hours Core Formulary contains the *minimum* list of drugs that patients should be able to access. Exact mechanisms for the provision of these drugs should be decided locally, taking into account existing treatment protocols. Whilst all the drugs identified in the formulary should be available in every locality, this does not necessarily mean that every organised provider of out-of-hours services needs to carry the full range of drugs - local agreement may determine that certain drugs are only held by a particular provider within that local health community. Where this is the case, however, the PCT will need to ensure that this does not compromise patients’ prompt and easy access to these drugs.

A2 This formulary is intended to be used for the duration of all designated out-of-hours periods (e.g. evenings, weekends and Bank Holidays). There are only a limited number of situations where treatment needs to be started without delay and it is therefore appropriate that a limited formulary of drugs can be used in an out-of-hours situation, without detrimental effect to the health of the patient. There is well-established evidence to indicate that, for all conditions (and their associated medicines) included on this list early treatment is either beneficial, or the drug will relieve symptoms of pain or discomfort.

A3 There is some flexibility and discretion in the choice and quantities of drugs to be made available in the local formulary however:

- drugs or treatments indicated with a tick should be available in the formulation specified. For example, paracetamol should be made available in formulations suitable to treat both adults and children; metoclopramide needs to be available in injectable form only;

- the exact choice of preparation and/or formulation should be agreed following local discussion;

- local circumstances may require additions to this list;
the course length of the drugs given should be adequate to allow for resolution of the condition presenting out-of-hours and/or sufficient to allow for an appropriate GP review or follow up. Some suggested lengths of treatment are indicated in the table below but manufacturers’ original packs should be used wherever possible;

- the local formulary should be endorsed and periodically reviewed by an appropriate multidisciplinary prescribing committee;

- where appropriate, certain items can be made available for supply by other health care professionals working to approved Patient Group Directions (PGD). Guidance and information on template PGDs can be found on the website: http://www.groupprotocols.org.uk/

- a copy of the National Out-of-Hours Formulary can also be found in the Drug Tariff Part XVIIC.

A4 PCTS should take proper account of patient safety issues by regularly consulting with latest guidance on the NPSA website – http://www.npsa.nhs.uk

A5 For full prescribing information and guidance all prescribers should consult the current British National Formulary http://www.bnf.org.uk/ or Summary of Product Characteristics.
## The Formulary Core Drug List

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
<th>Child</th>
<th>Adult</th>
<th>Injectable</th>
<th>Other</th>
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<tbody>
<tr>
<td><strong>Analgesia</strong></td>
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<td></td>
<td></td>
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<tr>
<td><strong>Codeine or equivalent</strong></td>
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<td></td>
<td></td>
<td>![checkmark]</td>
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<tr>
<td>Oral formulations to be supplied as a full course to appropriately treat the presenting condition. Codeine preferred as it has a dual role for pain relief and diarrhoea.</td>
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<td>![checkmark]</td>
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<tr>
<td><strong>Diamorphine</strong></td>
<td>![checkmark]</td>
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<td>![checkmark]</td>
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<tr>
<td>Diamorphine is preferred for its use in both cardiac pain and palliative care.</td>
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<td>![checkmark]</td>
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<tr>
<td><strong>Non Steroidal Anti-Inflammatory Drug (NSAID)</strong></td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td>![checkmark]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral formulations to be supplied as a full course to appropriately treat the presenting condition. The exact preparation(s) should be decided after local negotiation. Intramuscular injection of a NSAID may avoid the need for controlled drug use.</td>
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<td>![checkmark]</td>
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<tr>
<td><strong>Paracetamol</strong></td>
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<tr>
<td>Supply as a full course to appropriately treat the presenting condition.</td>
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<td>![checkmark]</td>
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<td><strong>Asthma</strong></td>
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<tr>
<td><strong>Inhaled Ipratropium</strong></td>
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<tr>
<td>Supply as a full course to appropriately treat the presenting condition.</td>
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<tr>
<td><strong>Inhaled Salbutamol or equivalent</strong></td>
<td>![checkmark]</td>
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<tr>
<td>Supply as a full course to appropriately treat the presenting condition.</td>
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<tr>
<td><strong>Prednisolone</strong></td>
<td>![checkmark]</td>
<td>![checkmark]</td>
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<tr>
<td>Oral formulations to be supplied as a full course to appropriately treat the presenting condition. Soluble tablets may be preferable for dual use in children and adults.</td>
<td></td>
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<td>![checkmark]</td>
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<tr>
<td><strong>Spacer Device</strong></td>
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<tr>
<td>Or nebuliser device.</td>
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</tbody>
</table>
The Formulary Core Drug List

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiac Emergencies</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Adrenaline/Epinephrine</strong></td>
<td></td>
</tr>
<tr>
<td>Strength/formulation suitable for treatment of cardiac arrest</td>
<td></td>
</tr>
<tr>
<td><strong>Aspirin</strong></td>
<td>✓</td>
</tr>
<tr>
<td>For use in all patients with suspected Myocardial Infarction unless contraindicated or already taken</td>
<td></td>
</tr>
<tr>
<td><strong>Atropine</strong></td>
<td>✓</td>
</tr>
<tr>
<td>For use in cardiac emergencies</td>
<td></td>
</tr>
<tr>
<td><strong>Diamorphine</strong></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Furosemide</strong></td>
<td>✓ ✓</td>
</tr>
<tr>
<td>Supply as a full course to appropriately treat the presenting condition Full course of oral tablets is expected to be 7 days maximum</td>
<td></td>
</tr>
<tr>
<td><strong>Glyceryl Trinitrate sub-lingual</strong></td>
<td>✓</td>
</tr>
<tr>
<td>Supply as a full course to appropriately treat the presenting condition</td>
<td></td>
</tr>
<tr>
<td><strong>Alergy/Anaphylaxis</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Adrenaline / Epinephrine</strong></td>
<td></td>
</tr>
<tr>
<td>Strength/formulation suitable for treatment of anaphylaxis</td>
<td></td>
</tr>
<tr>
<td><strong>Hydrocortisone</strong></td>
<td>✓</td>
</tr>
<tr>
<td>Hydrocortisone sodium succinate can be used for anaphylaxis, asthma and hypoadrenalism</td>
<td></td>
</tr>
<tr>
<td><strong>Chlorphenamine</strong></td>
<td>✓ ✓ ✓</td>
</tr>
<tr>
<td>Supply as a full course to appropriately treat the presenting condition</td>
<td></td>
</tr>
<tr>
<td><strong>Non-sedating antihistamine</strong></td>
<td>✓</td>
</tr>
<tr>
<td>Supply as a full course to appropriately treat the presenting condition. Choice of preparation to be decided locally.</td>
<td></td>
</tr>
</tbody>
</table>
### Diabetic Emergencies

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon Injection</td>
<td></td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
</tr>
<tr>
<td><strong>Current recommendation is for both Glucose IV and Glucagon to be carried. Children may not respond to Glucagon so are more likely to need glucose. Patients not responding should be admitted.</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Opioid Overdose

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone</td>
<td></td>
</tr>
<tr>
<td><strong>Any patient with an opioid overdose should be admitted to hospital, as repeated doses may be required.</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Gastrointestinal

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antacid</td>
<td></td>
</tr>
<tr>
<td><strong>Supply as a full course to appropriately treat the presenting condition taking into account manufacturers’ pack sizes.</strong></td>
<td></td>
</tr>
<tr>
<td>Domperidone</td>
<td></td>
</tr>
<tr>
<td><strong>Supply as a full course to appropriately treat the presenting condition (see also metoclopramide)</strong></td>
<td></td>
</tr>
<tr>
<td>Glycerol suppositories</td>
<td></td>
</tr>
<tr>
<td><strong>Included for immediate symptom relief (may be suitable for use by other healthcare professionals)</strong></td>
<td></td>
</tr>
<tr>
<td>Anti-spasmodic agent</td>
<td></td>
</tr>
<tr>
<td><strong>Supply as a full course to appropriately treat the presenting condition.</strong></td>
<td></td>
</tr>
<tr>
<td>Loperamide</td>
<td></td>
</tr>
<tr>
<td><strong>Supply as a full course to appropriately treat the presenting condition</strong></td>
<td></td>
</tr>
<tr>
<td>Metoclopramide</td>
<td></td>
</tr>
<tr>
<td><strong>Included as there is no parenteral formulation of domperidone</strong></td>
<td></td>
</tr>
</tbody>
</table>
The Formulary Core Drug List

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
</table>
| **Oral rehydration sachets**  
Supply as a full course to appropriately treat the presenting condition | ✓ ✓ |
| **Phosphate enema**  
Included for immediate symptom relief (may be suitable for use by other healthcare professionals) | ✓ |
| **Prochlorperazine**  
Oral formulations to be supplied as a full course to appropriately treat the presenting condition | ✓ ✓ ✓ |

### Psychiatric Emergencies/CNS

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
</table>
| **Diazepam**  
Supply as a full course to appropriately treat the presenting condition. Course length to be decided locally taking into account local policies and guidelines. Small quantities may be more appropriate. An appropriate rectal formulation to be included. | ✓ ✓ ✓ ✓ |
| **Haloperidol**  
Supply as a full course to appropriately treat the presenting condition. May also be used for treatment of severe nausea and vomiting. | ✓ ✓ |
| **Procyclidine**  
Supply as a full course to appropriately treat the presenting condition | ✓ ✓ |

### Obstetric and Gynaecology

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
</table>
| **Levonorgestrel 750**  
Full course to be supplied – included as current evidence suggests early treatment is appropriate | ✓ |
| **Syntometrine injection**  
Rarely used but essential to have available for intra or post partum obstetric emergencies. Special storage arrangements may be necessary | ✓ |
## The Formulary Core Drug List

### Palliative Care Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Child</th>
<th>Adult</th>
<th>Injectable</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diamorphine</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyclizine</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyoscine butylbromide</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketorolac/diclofenac</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methotrimeprazine/ Levomepromazine</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Midazolam**

It is expected that these drugs would be part of a special tamper proof palliative care pack that would be locally available. Local discussions will be necessary to determine appropriate access. The quantities supplied should be enough to allow appropriate symptom relief until formal review by palliative care team or General Practitioner.
The Formulary Core Drug List

Following local discussion, antibiotics should be made available to appropriately treat the conditions listed below. Choice of preparation(s) should take into account local resistance patterns.

### Local Antibiotic Choice

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>ORAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellulitis and other skin infections</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory infections</strong></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Upper respiratory tract infections</strong></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Urinary tract infections</strong></td>
<td>✓</td>
</tr>
<tr>
<td>Supply as a full course to appropriately treat the presenting condition. Choice of preparation(s) should be made after local discussion taking into account local resistance patterns.</td>
<td></td>
</tr>
</tbody>
</table>

### Infection

#### Bacterial conjunctivitis
Supply as a full course to appropriately treat the presenting condition. Choice of preparation(s) should be made after local discussion taking into account local resistance patterns.

#### Candidiasis (Topical)
Included for immediate symptom relief

#### Herpes Zoster
Supply as a full course to appropriately treat the presenting condition, choice of preparation to be decided locally. Included as current evidence suggest early treatment is appropriate.

#### Benzylpenicillin
For immediate treatment of meningococcal meningitis or septicaemia. Patients with suspected meningitis should be transferred to hospital urgently.

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24 See the Health Protection Agency document **Management of Infection Guidance for Primary Care for Consultation and Local Adaptation** at [http://www.hpa.org.uk/infections/topics_az/primary_care_guidance/menu.htm](http://www.hpa.org.uk/infections/topics_az/primary_care_guidance/menu.htm)
The Formulary Core Drug List

<table>
<thead>
<tr>
<th>Drug &amp; Comments</th>
<th>Child</th>
<th>Adult</th>
<th>Injectable</th>
<th>Other</th>
</tr>
</thead>
</table>

**Miscellaneous**

**Sodium chloride for injection/infusion**
*Also to include IV giving set and canula*

**Water for injection**
*For dissolving injectable drugs*

**Blood glucose testing sticks**
*Use where diagnosis cannot safely wait e.g. to identify patients who have urgent treatment needs or who should be admitted to hospital.*

**Urine testing sticks**
*Use where diagnosis cannot safely wait e.g. to identify patients who have urgent treatment needs or who should be admitted to hospital.*

**Drugs where special arrangements may be appropriate**

**Oxygen**
*It may be appropriate for some organisations to keep a supply of oxygen. Alternatively, local discussion and specific arrangements will need to be made for the delivery and set up of oxygen.*
Sources

The sources of information detailed below were used to produce the minimum list of drugs which were considered for inclusion in the National Out-of-Hours Formulary. This draft list was then shared several times with a number of stakeholders and organised providers until a broad consensus on the content was reached. The minimum list of drugs identified above is considered to be sufficient to be able to meet urgent patient needs in whichever geographical setting they are used.


*Drugs for the Doctors Bag* – D & TB Vol. 38 No 9 – September 2000

*The Development of a GP Formulary of Drugs for Out-of-Hours Care.*

*Out-of-Hours Formulary* – Healthcall, Meddoc, Harmoni, Nordoc, Sheffield GP Co-operative


*Out-of-Hours Palliative Care in the Community.* Dr Keri Thomas – March 2001.

*South Thames Guidelines for Management of Common Medical Emergencies in General Practice.*
Oriana Dwight, Joe Collier (Eds) – 1998. To be updated Nov 2004

*Prodigy Guidelines* [http://www.prodigy.nhs.uk](http://www.prodigy.nhs.uk)

*Electronic Medicines Compendium* [http://www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)
[http://www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)

*Patient Safety Alerts* [http://NPSA](http://NPSA)

Resuscitation Council website [http://www.resus.org.uk/siteindex.htm](http://www.resus.org.uk/siteindex.htm)