NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
Patient Group Directions Good Practice Guidance

Guidance Development Group (GDG)

Terms of Reference

Background to the project

This project is concerned with the systems and processes and legislation associated with developing, authorising, using and updating Patient Group Directions (PGDs) by providers of NHS services.

A PGD provides a legal mechanism by which medicines can be supplied and/or administered to patients by a specified range of healthcare professionals, without first seeing a doctor or dentist, provided they fit the criteria laid out in the PGD. Organisations authorising PGDs also have a responsibility to ensure that only fully competent and trained registered healthcare professionals use PGDs.

Changes to NHS organisational structures, and to the way in which healthcare services are delivered, mean that amendments to medicines legislation are required to enable the continued use of PGDs after April 2013, when PCTs will cease to exist. PGDs authorised by PCTs and used to deliver NHS services will no longer be valid.

Local authorities will take on responsibility for public health improvement services such as sexual health and smoking cessation, and other services will come under the umbrella of Public Health England. A wide range of other service delivery frameworks are also developing, with increasing use of independent providers such as community pharmacies and social enterprises to deliver NHS services.

The Department of Health and MHRA are preparing amendments to medicines legislation to enable PGDs to be authorised by or, on behalf of, those organisations taking over the responsibilities of PCTs or other new bodies emerging, such as Clinical Commissioning Groups, NHS Commissioning Board, Public Health England and local authorities.

Furthermore, The Human Medicines Regulations 2012 came into force on the 14th August 2012. Policy changes include an update to the process by which independent hospitals, clinics and agencies are able to continue using PGDs to ensure processes reflect changes to the registration requirements for organisations.

The National Prescribing Centre (NPC) publication 'Patient Group Directions – a practical guide and framework of competencies for all professionals using patient group directions' (December 2009), is the most recent reference source for organisations and individuals. However, this requires updating to reflect new medicines legislation, new NHS organisational structures and the increasing range of providers of services to NHS patients.

Scope

The good practice guidance will cover the systems, processes and legislation relating to developing, authorising, using and updating PGDs by providers of NHS services. It will not cover Patient Specific Directions (PSDs) or other mechanisms for the supply of medicines to patients. It will not cover wider issues of commissioning services and service provision.

It will also not include shared practice examples or other suggested methods for implementation of the good practice recommendations. These aspects will be for local development within organisations authorising PGDs.

This guidance will be written in the context of the NHS in England, though it will be applicable as NICE Guidance, as appropriate, to some of the devolved administrations.

Purpose

The guidance development group will be the primary source of expertise to determine the content and shape the production of NICE good practice guidance for patient group directions, as defined within the scope of the project.

Timescales

Group members are expected to attend up to 4 meetings throughout the document development process, although only 3 are currently planned. The process is expected to be completed by the end of March 2013. Group members may also be required to attend a working group that may be associated with the GDG and will be expected to contribute to virtual discussions and occasional teleconferences as appropriate. In addition, group members will need to be able to deal in a timely manner with the reading of draft documents as well as advising with the production of consultation documents.

Membership

Following the appropriate application and selection process the individuals below have been recruited to the GDG in addition to staff from the NICE project team.

Name	Organisation
Angela Bussey	Guy's Hospital, Guy's and St Thomas' NHS Foundation Trust
Joyce Calam	Lay representative
Martin England	Ashtons Hospital Pharmacy Services
Katherine Gough	NHS Dorset and NHS Bournemouth and Poole
Alan Hughes	Betsi Cadwaladr University Health Board
Jonathan Mason	NHS North East London and the City
Ivor Nathan	Lay representative
Julian Newell	Barnsley Hospital
Shelley Raine	Consultant
Stephen Riley	Medicines Optimisation Ltd
Helen Stubbs	NHS Merseyside
Jane Swan	Nottinghamshire Healthcare NHS Trust

The group may invite individuals to a meeting to present evidence or to add value to a particular discussion.

Meeting arrangements / communication

The following meetings are currently scheduled for the GDG:

Thursday 13th December – Liverpool
Tuesday 8th January – London
Tuesday 26th February – Manchester

Additional communication will likely be via email and teleconference although the group may decide additional face to face meetings are required. It is the responsibility of group members to inform NICE (via the project team) of any changes to contact information.

Responsibility of members

Members will

- contribute to the identification of evidence sources and assessment of evidence for good practice for the development of NICE good practice guidance for patient group directions
- shape and input into the development of good practice guidance in a way consistent with the development process
- ensure the good practice guidance meets the needs of providers of NHS services and stakeholders and is developed within the bounds of NICE processes and the scope of the project
- attend GDG meetings in person
- adhere to relevant NICE policies (for example, declarations of interest, expenses).

Members cannot submit comments as either a stakeholder or as part of the formal consultation.

People are GDG members in their own right and do not represent any particular organisation or group.

Confidentiality

GDG Members undertake to NICE that they shall:

- keep all confidential information strictly confidential
- not use any confidential information for any purpose other than participating in the deliberations of the GDG
- not disclose any confidential information to any third party without the prior written consent of NICE and in the event that such disclosure is permitted shall ensure that such third party is fully aware of and agrees to be bound by these undertakings
- not disclose the deliberations of a GDG to any other person without the explicit consent of the Chair of the GDG and the Programme Director of the NICE Medicines and Prescribing Centre.

The undertakings set out above ('the undertakings') shall not apply to the use or disclosure of information that:

- at or after the time of disclosure or acquisition is in the public domain in the form supplied otherwise than through a breach of any of the undertakings; or
- was lawfully within the member's possession before its disclosure to them by NICE provided that the source of such information was not bound by, or subject to, a confidentiality agreement with NICE; or
- the member is required to disclosure by any court of competent jurisdiction or any government agency lawfully requesting the same, provided that they notify NICE in advance of such disclosure; or
- is approved for release by prior written authorisation from NICE.

Accountability

The group is accountable to the Programme Director of the Medicines and Prescribing Centre, part of the Centre for Clinical Practice, NICE.