



Pharmaceutical Information and Pharmacovigilance Association (PIPA) UK Guidelines on Standards for Medical Information Departments (Revised 2006)

These guidelines should be read in conjunction with the MHRA Blue Guide and the ABPI Code of Practice.

Introduction

High quality up-to-date information about medicines is essential for their safe and effective use in treating patients. Pharmaceutical company medical information departments are a leading source of such information, including information that is not available from other sources. The importance of this role is recognised in the ABPI Code of Practice* (Clause 13), which states that companies must have a scientific service that is responsible for information about medicines which they market.

Appreciating the need for high standards in the provision of medical information, PIPA has drawn up the following guidelines after consultation with key customers. The original guidelines were written in 1995, with the latest revision in 2006.

Adherence to the guidelines is necessarily voluntary. They are however recommended to all companies as representing practicable standards indicative of a high quality of service in medical information.

*The Code of Practice reflects the requirement for a scientific service in charge of information laid down in the European Directive on Advertising of Medicinal Products for Human Use (92/28/EEC) and the UK Medicines (Advertising) Regulations 1994.

Access to the medical information service

Companies must have a clearly identified resource to deal with medical, pharmaceutical, and technical enquiries.

The telephone number(s) of the medical information service should be advertised in appropriate publications, such as the ABPI Medicines Compendium, MIMS, the British National Formulary and BNF for Children (and their electronic versions), and the UK Company website. Where appropriate, a direct-dial number to medical information should be used.

Any medical information provided via either an open or password protected website should comply with these guidelines and with the ABPI Code of Practice.

Procedures for handling enquiries

Procedures should be in place to ensure that customers are routed to the appropriate department as rapidly as possible.

Procedures should be in place for answering enquiries from healthcare professionals, from patients and the public, and from other groups, eg, press, police, coroners, and solicitors.

A standard procedure should be in place for handling telephone calls covering:

- *Speed of response* - calls should be answered with minimal delay. The use of answering machines, voice-mail, and interactive voice routing (IVR) systems to deal with medical information enquiries should be avoided. However, if direct-dial answering machines or voice-mail systems are used, there must be an automatic re-routing facility or alternative number for callers to obtain an immediate response in emergencies. If IVR systems are used, the menus should be kept to a minimum.
- *Identification of the person answering the call* - it must be made clear immediately to the caller whether he/she is talking to a person who will be able to answer the enquiry or to someone who will take a message. Where company policy permits, it is recommended that medical information personnel identify themselves by name to customers.
- *Manner* - persons answering telephone calls must at all times be helpful, courteous, and easily understood.
- *Enquiry details* - staff should be appropriately trained and/or use prompt lists when taking details of telephone enquiries to help ensure that they are properly understood and that sufficient details are taken.
- *Call transfers* - transferring calls inconveniences callers and should be avoided or, if essential, kept to the absolute minimum (ideally no more than one transfer within or from the department). Relevant details should be provided to the recipient of the call.
- *Putting customers "on hold"* - if it is clear that it may take longer than 2 minutes to answer the customer's question, then he/she should be told this and given the option of holding or being rung back by an agreed time.
- *Return calls* - if a return call has to be made to the enquirer a deadline for this must be agreed and adhered to.
- *Cover* - there must be a procedure to ensure that appropriate staff are available or can easily be contacted throughout office hours, including lunch times, and that deputies are available when staff are out of the office, eg, during holiday periods. An appropriate procedure must also be in place to deal with emergency out-of-hours enquiries (evenings, weekends, public holidays, etc.).

All reasonable steps must be taken to identify enquirers, who should be answered in accordance with their status or profession.

If an internal call centre is used the staff must be suitably trained to recognise adverse events and deal with them appropriately. If the first line triage is not done by a medical information professional there should be clarity regarding when calls are escalated to Medical Information.

Letters, faxes and e-mails must be read promptly and dealt with appropriately. Where possible, e-mails should be acknowledged promptly.

The answer and any subsequent follow-up should be supplied within a deadline agreed with the enquirer. If a response cannot be supplied by the deadline, the enquirer should be notified that there will be a delay and should be given the reason and a new deadline.

In the absence of an agreed deadline, enquiries should be answered as quickly as possible. A reasonable standard may be five to ten working days depending on the nature and complexity of the enquiry. The enquirer should be notified if there will be a delay.

A procedure must be in place to ensure that urgent requests on safety or other issues are expedited.

Each company's organisational structure and policies will define the appropriate process for handling enquiries from overseas.

It is recognised that the marketing authorisation holder may not always directly market or sell the product. A third party may be involved. In such cases, agreements should be in place to clearly define which company is delivering the medical information and pharmacovigilance services.

A policy should be agreed with the company's legal department on the length of time, types of enquiries, and what level of detail should be retained for legal, regulatory audit, and potential litigation purposes. Such records may include:

- details of the enquirer
- the nature of the enquiry
- when it was received
- the degree of urgency
- referral to other departments or individuals
- details of information provided
- who provided the information and when
- any follow-up

If a third party is used to provide customer responses on behalf of the Medical Information department (ie, outsourcing) there should be defined working practices and resources in place to ensure that the devolved service levels meet industry standards.

Supply of information to healthcare professionals

Companies should have a procedure to ensure the most current prescribing information is displayed in relevant hardcopy and electronic publications. Details of changes to Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) should be sent to publications such as the electronic Medicines Compendium website (www.medicines.org.uk), MIMS and electronic MIMS (www.emims.net), BNF and BNF for Children, Chemist & Druggist, and Pharmaceutical Journal. Additional methods of supplying SmPCs and PILs to healthcare professionals and the public (eg, post, via representative, e-mail, Internet) may be used as appropriate and as permitted by current legislation and codes of practice.

To facilitate safe dispensing of products, all healthcare professionals involved in dispensing, including community pharmacists, require prior warning of new product launches. It is standard practice for companies to send letters to wholesalers, after licence but before launch, to enable stock purchase. Companies should also circulate wholesaler letters to groups such as the National Pharmaceutical Association (www.npa.co.uk) and the UK Medicines Information network (www.ukmi.nhs.uk). All letters should be accompanied by full prescribing information and PIL where possible.

When products are discontinued, changed, or divested, medicines information centres (www.ukmi.nhs.uk) must be promptly notified directly or via the pharmaceutical press. In the case of divested products a procedure must be agreed for transfer of information to the new owner to enable that company to maintain an adequate medical information service. For discontinued products, the DoH/ABPI Best Practice Guidelines for discontinuation should be followed (www.doh.gov.uk/discontinuedmedicines/discontinuedmedicines.pdf).

A procedure should be in place to notify appropriate medical staff and pharmacists of urgent important information, eg, availability, contra-indications, warnings, and adverse effects. UK Medicines Information centres may be notified via NeLM using the address nelm@gstt.nhs.uk.

Requests from external customers for information relating solely to another company's product should be referred promptly to that company.

In some instances a company may receive an enquiry about a parallel imported product for which they do not hold the licence in the UK. The enquirer may be redirected to the company holding the licence in the UK or the company importing the product.

In response to a request for advice on the treatment of an individual patient using a prescribed medicine, factual information may be given. The decision about treatment remains the responsibility of the patient's prescriber. Medical Information departments should be aware of the needs of healthcare professionals and should be as helpful as possible in sharing expertise, knowledge, and information to aid decision-making. If a medical opinion is required the enquirer should be referred to a company medical adviser or other medically qualified person.

Information provided should be within the terms of the product licence. However, information may be supplied in response to unsolicited enquiries, from health care professionals, related to off-label use or unlicensed drugs. Objective, factual, and non-promotional information regarding a product's off label use might only be available from the manufacturer or marketing company and this will usually be via the Medical department. It is important that the prescriber is made fully aware of the label status and appreciates that use of a product outside its licence is the responsibility of the prescriber.

Information on new drugs before marketing or on unlicensed products may be provided to healthcare personnel on request. Information may also be provided pro-actively to those involved in planning the introduction of new products provided that this complies with the supplementary information to Clause 3.1 of the ABPI Code of Practice.

Enquiries from the public

People are increasingly aware of and involved in their own medical care, and information of a medical nature is becoming more accessible (eg, via NHS Direct or the Internet). This means that patients who are already well informed about their condition and its treatment may be contacting companies. Their current level of knowledge about their treatment should be assessed before any information is given.

Enquiries from the public, including patients, must be handled in accordance with the requirements of the ABPI Code of Practice (specifically Clause 20). Such enquiries must be answered with care and judgement. Factual information about a medicine may be given. A decision must be taken in each case as to whether the company can responsibly answer the enquiry or recommend that the patient consult their doctor, pharmacist, or other healthcare professional as appropriate.

Many health information and patient organisations now exist and it may be appropriate to give details to members of the public so that they may obtain more information about specific conditions. There are also a number of publicly available documents which might be appropriate, eg, SmPCs, PILs, EPARs (European Public Assessment Report).

Additional information may be provided in response to public enquiries about General Sales List (GSL) or Pharmacy only (P) products. As the public are exposed to claims about efficacy, relevant factual information can be provided depending upon company procedures. However the information provided must not be promotional or be seen to be making any promises regarding efficacy and safety. Any enquiries regarding the use of GSL/P products in patients with concomitant illness or taking other medicines should be referred to their doctor, pharmacist, or other healthcare professional.

In some situations when people request information on personal medical matters it may be appropriate to provide information directly to their doctor such that they can discuss it at their next visit. Under such circumstances permission must be obtained from the patient. The nature of the enquiry and the limitations placed on the company in supplying information directly to the patient must be explained to the doctor.

Some enquiries from the public may alert the company to possible adverse reactions that have occurred in association with the use of a specific product. In such situations permission must be sought from the patient to contact their doctor, and the company's usual pharmacovigilance procedures must be initiated.

Enquiries about possible adverse reactions

Enquiries about adverse reactions, overdose, misuse or maladministration, or use during pregnancy or lactation concerning any of the company's products may require involvement of the company's pharmacovigilance function. If the enquiry is of a general nature, and no patient has experienced an adverse reaction with a specific product nor has it been used in a pregnant patient, the enquiry should be handled in accordance with the usual methods for answering enquiries of a clinical nature.

Adverse events or overdose: it is good practice to establish whether the enquiry concerns the clinical use of any of the company's POM, GSL, and P products, and devices. If so, details of the adverse event(s) should be taken, and the company's pharmacovigilance procedure followed. The National Poisons Information Service may be an additional resource for enquirers dealing with overdoses.

Use during pregnancy: it should be established whether the enquiry involves use of any of the company's products in a pregnant patient. If so, details should be taken and the case followed up in accordance with the company's usual process for obtaining such information; *companies should actively seek information about the outcome of pregnancies following use of any of their products.*

See information related to the handling of adverse events in the PIPA UK Standards in Pharmacovigilance (2005) at:

www.pipaonline.org/downloads/uk_standards_in_pharmacovigilance_2005.doc

Information resources

Medical Information departments must have a minimum set of up-to-date information resources to enable them to provide comprehensive information on all the products for which they are responsible. Further guidance on recommended textbooks and electronic sources is provided by PIPA (see www.pipaonline.org).

Medical Information departments must be able to easily identify published references on the products for which they are responsible. They must also have access to relevant unpublished information where it exists, including adverse reaction reports, pharmaceutical information such as stability studies, and clinical data.

Information professionals must have (or have ready access to) detailed knowledge on the products supplied by their company. There should always be someone available to provide a knowledgeable response in the absence of the recognised product expert.

A procedure must be in place to ensure that information resources are kept up-to-date.

For discontinued products only concise product histories (eg, alternative suppliers where appropriate) need to be kept.

There is no obligation for a company to provide information on another company's product containing the same active ingredient. In some cases there may be risks in doing so as excipients and other aspects of the formulation may differ.

Enquiries via third parties

Information requested via a third party such as a sales representative is usually sent directly to the customer. If agreed by the customer, it could also be sent via the sales representative (however this could vary from company to company). In this case the sales representative is acting solely as a messenger and should not be providing the information in a promotional manner. It may be good practice to document the route by which information has been sent.

Medical Information booths or stands at external conferences

It is acceptable for medical information staff to attend external conferences to be available to handle enquiries from attendees such as HCPs. Efforts should be made to ensure that enquiries are handled in accordance with the Code of Practice.

Qualifications and training

Medical information professionals should have suitable qualifications or experience. This would normally be a degree in pharmacy, pharmacology, or a life science, or an appropriate equivalent qualification or experience.

All medical information professionals must receive training appropriate to the level of their responsibilities. They should have an up-to-date working knowledge of the following subjects if they have not been covered in previous training, academic studies or job experience:

- pharmacy and pharmacology
- drug development
- areas of medicine related to products for which they are responsible
- information sources and information technology
- evaluation and assimilation of information
- communication skills and written presentation of information
- pharmacovigilance
- regulatory affairs
- regulations and codes of practice
- health economics and evidence-based medicine
- customer care
- public relations and marketing of medicines
- copyright permissions and restrictions
- data protection legislation

It is good practice to maintain job descriptions, induction programmes and training records for all job roles.

Quality standards

Medical information staff must demonstrate high standards of customer care, with a helpful and responsible attitude, and effective communication skills.

Medical information departments must set and monitor compliance with quality standards, which should include the following:

- that any written response does not contravene the Code or other statutory requirements
- information supplied must be accurate, fair, objective, unambiguous, and up-to-date and must reflect all the available evidence clearly
- comparisons between products must be based on an objective review of all the evidence and must reflect that evidence fairly - differences between products must not be exaggerated
- information must be relevant to the enquiry and the specific needs of the enquirer
- any additional product-related information supplied that is not directly relevant to the enquiry must be treated as promotional material, must comply fully with the ABPI Code of Practice, and must be appropriately certified
- for those enquiries requiring a literature search, a search record should be maintained and details should be provided to the enquirer if appropriate
- the term "Medical Information" must not be used to describe promotional materials or materials used for promotional purposes

- Companies should put into place a procedure to encourage feedback and deal with complaints about their medical information service.

Audits and performance indicators

Medical information departments must have appropriate systems in place to monitor their performance and should carry out audits at regular intervals. Appropriate performance indicators include the following:

- telephone calls should be answered quickly (within five rings)
- during office hours appropriate staff must be available to deal with telephone enquiries at all times or must be able to be reached with minimal delay (no more than five minutes) when information is required urgently
- enquiries requiring a written response should be answered in a timely manner or by a deadline agreed with the enquirer. In the absence of an agreed deadline, a reasonable standard may be five working days for straightforward enquiries and ten working days for more complicated enquiries
- customers' views of the quality of service and information provided should be assessed periodically, for example, by questionnaires relating to specific enquiries or surveys. An industry standard questionnaire should be used to encourage benchmarking. Additional questions can be added to the core questions
- for appropriate enquiries, feedback should be obtained from the enquirer on the value of the information provided - how it was used and what actions/decisions were taken because of it

For the current version of this document, please consult the PIPA website (www.pipaonline.org).

Produced in association with the ABPI and UKMi.

© **Pharmaceutical Information and Pharmacovigilance Association (PIPA)**

2006