Reprint from PIPELINE Issue 43, February 2014
©Copyright Pharmaceutical Information and Pharmacovigilance Association

All rights reserved

PIPA "UK Guidelines for the Pharmaceutical Industry Medical Information Departments" update

Sarah Dunnett – Senior Medical Affairs Manager, Baxter and PIPA President


Sarah Dunnett

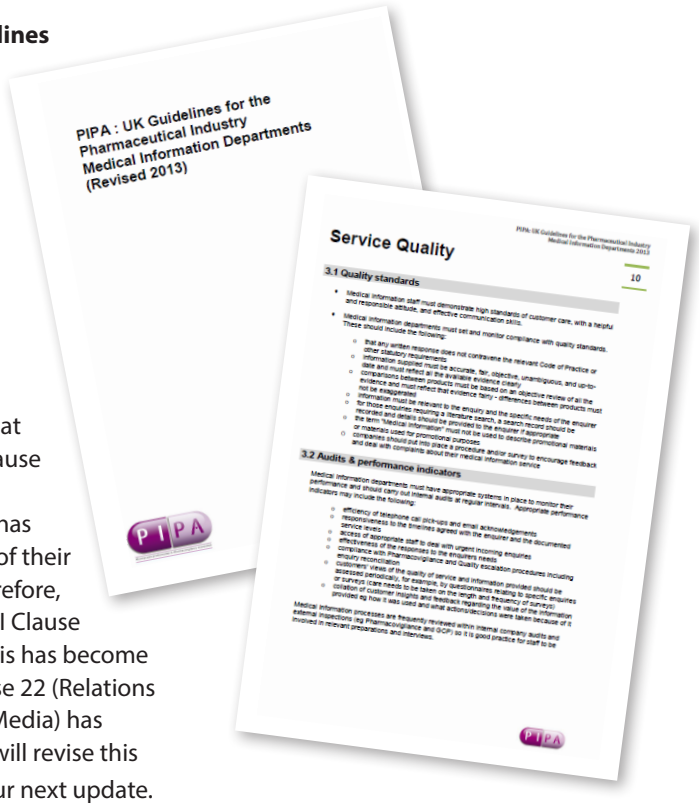
In October 2013, we announced the publication of our new guidelines for Medical Information practice via our e-news alert. These guidelines are always available to PIPA members on the website.

Medical Info updates

Appreciating the need for high standards in the provision of medical information, PIPA drew up and revised these guidelines after consultation with key customers. The original guidelines were written in 1995, revised in 2006 and this third edition was completed in Autumn 2013. The current edition reflects a comprehensive overhaul and re-organisation of the document. We have segmented the content into clear numbered sections to facilitate cross-referencing within company procedures and tried to appropriately represent the changes in business and customer expectation, technology, Codes of Practice and legislation, most notably the EU Pharmacovigilance modules. While they may be entitled as UK Guidance, we are delighted that they are widely recognised by MI and PV professionals across Europe and World-wide.

Compliance with these PIPA guidelines is voluntary. However, they are recommended to all pharmaceutical companies as representing practicable standards indicative of a high quality of service in medical information. Our UKMI customers are in touch with these guidelines and may well be expectant of the service levels described.

These guidelines are intended to compliment PIPA's sister publications, the "Guidelines for Pharmacovigilance Departments" and the "Guidelines for Signal Management" - both available in the members section of the PIPA website. They should be read in conjunction with the current MHRA Blue Guide, the ABPI PMCPA Code of Practice and the ABHI Code of Business Practice. We recognise that the inclusion of a new clause to the January 2014 ABPI PMCPA Code of Practice has affected the numbering of their subsequent clauses. Therefore, when we referred to ABPI Clause 21 (Scientific Services) this has become Clause 22 and ABPI Clause 22 (Relations with the Public and the Media) has become Clause 23 – we will revise this cross-referencing with our next update.



There will obviously be some debate as to which aspects should be mandatory and which expressed as best practice – indeed, we considered this during the review phase. We'd really welcome your perspectives on whether we have pitched this appropriately for your services. Equally, we'd welcome your suggestions for future updates to the guidelines – are there any gaps or areas that you disagree with or would like expanded? Please visit the Discussion Room on the website to share your thoughts on this – a discussion thread has been started to capture your comments.

Philip Ball, Medical Information Manager at Napp, decided to review the new guidelines in comparison to earlier editions and drew a list of the most significant aspects from his perspective. While this was primarily to assist implementation by his own team, in line with PIPA's sharing ethos, he kindly forwarded his observations so we could include them within PIPEline. His summary is intended as a quick guide only; it paraphrases sections of the guidelines and should not be used in lieu of reading the original document. Phil highlights new content within the 2013 guidelines with ***bold italics***.

Click here to go to Contents page

General

- The guidelines have been split into specific numbered sections.
- The guidelines now refer to medicines ***and devices.***

1.1 Service Access

- The MI Department contact details to be published have been expanded from "telephone number" only to "telephone number***, email and postal address".***
- The recommended place for these to be published has been expanded to encompass MIMMs, BNF, ***online product databases*** and the UK company website.
- Where possible, a ***direct-dial number for Medical Information*** should be provided.
- A procedure must be in place to ensure that staff can be easily contacted during normal office hours, including lunchtimes, ***and that cover is available during holiday periods.***
- ***It is good practice to inform any multi-day closure dates on the company website. Also, to publish emergency contact details on the company website.***
- ***It is good practice for Medical Information departments to maintain and test a documented business continuity plan i.e. for widespread staff sickness, database or phone failures or restricted office access.***

1.2 Procedures for handling enquiries

- All staff must be trained to recognise potential adverse events and ***quality complaints.***
- Calls should be answered with minimal delay ***(as a guide, 18 seconds).***
- ***It is good practice to ascertain the callers understanding of the appropriate sections of the SmPC or PIL (as appropriate) in relation to the enquiry.***
- ***In relation to adverse events and quality complaints – it is good practice to establish whether the caller has contacted the department previously.***
- ***All steps must be taken to identify an enquirer at the start of the call***

1.3 Information for Healthcare Professionals

- When providing off-label information: ***"it is important to determine whether or not the product has actually been used off-label and, if so, the relevant information must be passed onto the pharmacovigilance team"*** (i.e. departments should report confirmed cases of off-label use to their drug safety department).

1.4 Enquiries from the public

- Enquiries from the public may alert the company to potential adverse events that have occurred… ***"or other safety data that needs to be collected."***

1.5 Information resources

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

1.6 Enquiries via this parties

- Clarifies good practice in the delivery of the reponse

1.7 Medical Information booths & stands at external conferences

- The medical information booth or stand should be non-promotional in nature and efforts should be made to ensure that enquiries are always handled in accordance with the relevant code of practice and in a non-promotional style. Medical Information staff should have their role clearly identified on their name badge and should not staff promotional stands if they are present in a medical information capacity.

1.8 Potential adverse events & product complaints

- ***Significantly updated in light of the EU Legislation changes.***
- Wording now refers to adverse events and ***product complaints*** throughout.
- ***Reports of adverse events should be taken whether or not the product was used within its licence***
- The list of situations where safety information should be captured has been expanded – and includes ***confirmed cases of off-label use.***
- The PIPA Guidelines for PV and Signal Detection are referenced.

1.9 Data privacy & copyright

- ***A new section has been added dealing with data protection*** – see relevant section in full.
- ***It is good practice for a data privacy statement to be shared eg automated message before the caller reaches the call handler, within email acknowledgements***
- All enquiry responses must comply with copyright legislation and any restrictions defined by specific publishers.

2.1 Qualifications & training

Additional information has been added to the qualifications and training section, which includes the following

- Pharmacovigilance ***regulations and processes***
- Regulations and ***promotional*** codes of practice
- ***Market access, including reimbursement***
- Copyright ***legislation***
- ***NHS organisation***

Further wording has been added around ***clear personal development plans*** and CPD capture – the latter part is particularly in line with the new MPIPA and FPIPA recognitions related to the PIPA CPD scheme.

3.1 Quality standards

Minor amends only

3.2 Audits and performance indicators

Suggested performance indicators have been updated. Recommended that MI staff are ***involved in relevant preparations and interviews for external PV inspections as well as internal company audits.***

Click here to go to Contents page