

Strategic medical writing in the post-authorisation phase

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Abstract

This article outlines the latest legislation for some of the most common post-authorisation documents (Risk Management Plans, Periodic Safety Update Reports, and Post-authorisation Safety Studies) and explains the role of the strategic medical writer. The strengthening of post-authorisation legislation has led to documents with new and improved formats. At the same time, the strategic medical writer's role has evolved almost in parallel with these legislative changes. The strategic medical writer contributes document and scientific expertise, writing skills, and project leadership through effective communication, and also provides an invaluable link in the team in the development of post-authorisation documents by anticipating problems, managing the review process, advising on data presentation, and ensuring compliance with guidelines. This process results in the production of high-quality documents, makes the submission process smoother, promotes the strengthening of the pharmacovigilance system, and ultimately contributes to patient safety.

Keywords: Post-authorisation documents, Legislation, Medical writing, Pharmacovigilance

Introduction

Thalidomide was marketed following tests carried out in animals and was sold without prescription. The first child affected by thalidomide was born in the late 1950s,¹ but it was not until 1960 that neuro-pathic side effects were first reported, in the UK.² In 1961, following a sudden increase in cases of phocomelia, a German paediatrician noted that 50% of these patients had been exposed to thalidomide. It was not until 2 months later that the drug was withdrawn from the market, and the UK Ministry of Health issued a statement warning patients to stop taking the drug. However, the drug was not removed from sale. At this juncture there were up to 5000 reported deformities in the UK and 10 000

worldwide.³ There was a flaw in the system and it was clear that legislation was required to ensure patient safety and regulate the pharmaceutical industry. Proposals for new legislation to control medicines in the UK were published in 1967 and the outcome of these proposals was the Medicines Act 1968.⁴ The Act established legislation that required all medicines already marketed to undergo peer review and subsequent approval or withdrawal. In addition, the Act required that from 1971 all new medicines underwent a pre-marketing assessment for safety, quality, and efficacy by the licensing authority.

The history of thalidomide emphasises the vulnerability of patients. In addition, it highlights the requirement to understand the mechanism of action of a drug and its related toxicities,⁵ in conjunction with the necessity for legislation, not only before authorisation but also in the post-authorisation phase. The post-marketing arena is vital to ensure the safety of patients and the effectiveness of medicines in real-life settings. This is achieved by monitoring adverse events, and evaluating the benefit-risk profile of a medicine. This process includes the production and submission of documents such as Risk Management Plans (RMPs), Periodic Safety Update Reports/Periodic Benefit Risk Evaluation Reports (PSURs/PBRERs), and Post-Authorisation Safety Studies (PASSs) to the authorities by the marketing authorisation holder (MAH). The medical writer can play an important role in the preparation of these documents. However, recent legislation and the new and more complex format of the documentation demand more than just organising and formatting data. This provides an ideal opportunity for the strategic medical writer to add value to the documents by developing 'effective communication, arising out of the teamwork between the authors and the medical writer',^{6,7} to produce high-quality post-authorisation documents and ensure a smooth submission process.

This article outlines the latest legislation and explains the role of the strategic medical writer in some of the most common post-authorisation documents.

Legislation

Historically, the EMA has been criticised for its deficiencies. These have included inconsistency and a paucity of robustness in information and assessment, as well as insufficient transparency.^{8,9} However, the regulatory environment is changing. In 2012, the biggest change to human medicine legislation since 1995 was instigated. This resulted in the strengthening of pharmacovigilance legislation and demand for increased transparency of regulatory decision making. The key changes to the legislation are shown in Table 1.¹⁰

The changes impact the entire product lifecycle and will take time to fully implement.¹⁰ Amendments made to Directive 2001/83/EC (the community code relating to medicinal products for human use)¹¹ and Regulation (EC) No 726/2004 (laying down community procedures for the authorisation and supervision of medicinal products for human use and establishing an EMA)¹² have improved and generated changes in the pharmacovigilance system. These include risk evaluation and harmonisation of regulatory action on drug safety.¹³ The new legislation defines the roles and responsibilities for key responsible parties, rationalises EU decision making on drug safety issues to prevent unwarranted patient exposure to risks, increases transparency and communication of medicine safety, and strengthens companies' pharmacovigilance systems. The legislation ensures structured risk management procedures and data collection, and makes companies legally liable to perform PASSs as well as post-authorisation efficacy studies. In addition, new EU pharmacovigilance legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU) amending Regulation (EU) No 726/2004 (pharmacovigilance of medicinal products for human use) increases the level of transparency of safety information. Submissions of PSURs are required more frequently and are required to assess product safety through the assessment of the benefit-risk profile of the drug.^{14–17}

As a result of the new legislation a Pharmacovigilance Risk Assessment Committee (PRAC) was established at the EMA in July 2012. The main responsibility of the PRAC is to provide recommendations relating to pharmacovigilance activities, including risk management systems. It is responsible for assessing all aspects of the risk management of medicines, including the risk of adverse reactions, while considering the therapeutic effect of

the medicine. The establishment of the PRAC strengthens the regulation of medicines, improves transparency and communication in pharmacovigilance, and contributes to the risk management process.^{18,19}

The role of the medical writer has evolved almost in parallel with the changing legislation. In the 1960s medical writing began to be formalised with the publication of style manuals and by the late 1990s guidelines were published to improve the quality of the reporting of randomised trials (the CONSORT Statement).^{20,21} Today the medical writer has a multi-faceted role, described by Limaye²² as the 'four pillars of medical writing' (document expertise, scientific expertise, writing skills, and project leadership), a role that reaches beyond an editorial function. The strategic medical writer fulfilling this multi-faceted role has a key position in the production and submission of the new post-authorisation documentation. This is because the new documentation has more complex data in larger amounts, and requires greater detail, additional analysis, and input from different specialties. In addition deadlines remain tight.

The changes in the legislation have major implications for post-marketing documentation (described in the following sections). In the past, the European Commission's pharmacovigilance guidelines were drawn up in accordance with Article 106 of Directive 2001/83/EC, known as volume 9A,²³ and PSURs were based on the guidance document ICH E2C. The application of the pharmacovigilance legislation (as of July 2012) has been replaced with the good pharmacovigilance practice (GVP) guideline.²⁴ The significant changes in post-authorisation documentation provide the opportunity for the strategic medical writer to become an invaluable link in the team.

Risk Management Plan

When an initial authorisation is obtained, the benefit-risk is considered positive for the target population for the specified indication. Post-marketing data are essential as the drug has not been used in the 'real-life setting'. Therefore, there will be potential risks that have not been identified, and there may be additional or greater risks for subsets of patients outside of the target population. Risk management involves risk detection, risk assessment, risk minimisation, and risk communication and should consider both the individual patient and the public health impact.

Risk management is an important part of post-marketing documentation. The strategic medical writer can anticipate problems, provide a central

Table 1: Key changes to human medicine legislation instigated in 2012

Areas of change	Measures	Key implications
Coordination of lists of medicines	<ul style="list-style-type: none"> Controlled lists of all EU products will be created to support EU medicines databases Coordination of safety monitoring 	<ul style="list-style-type: none"> Reports of suspected adverse drug reactions (ADRs) will be more effective at identifying safety issues Identified safety issues will be published and accessible
Authorisation requirements	<ul style="list-style-type: none"> Marketing authorisation (MA) dossiers submitted to the EMA will change: pharmacovigilance system description will be reduced A pharmacovigilance system master file (PSMF) that can be requested or inspected will be maintained by all companies 	<ul style="list-style-type: none"> Less variations to authorisation (a new process to coordinate assessment and processing of applications to change MA, meaning multiple submissions are no longer necessary) The marketing authorisation holder (MAH) has the responsibility to maintain an accurate PSMF
Reporting of ADRs	<ul style="list-style-type: none"> Patients in the EU have the right to report suspected side effects From 2016: legal endorsement of the use of International Organization for Standardization (ISO) standards ADR reports will come only from industry and national agencies 	<ul style="list-style-type: none"> All patients can report a suspected side effect Centralised reporting will allow the EMA to report suspected ADRs to the WHO on behalf of 30 member states
Signal detection	<ul style="list-style-type: none"> New legal obligation for the EMA, national regulatory agencies, and industry to analyse data to detect new or changing safety issues 	<ul style="list-style-type: none"> New or changing safety issues should be detected more quickly New advice and warnings will reach patient information leaflets more rapidly ADRs should be minimised
Inspections and audits	<ul style="list-style-type: none"> Strengthened EU coordination of inspection Regular audits of the EMA, national authorities, and industry 	<ul style="list-style-type: none"> Greater assurance of the quality of pharmacovigilance performed by industry and regulators
Risk Management Plan (RMP)	<ul style="list-style-type: none"> All new products will have an RMP that will include a safety specification, a pharmacovigilance plan, and risk minimisation safety and efficacy studies Post-Authorisation Safety Studies (PASSs) will be legally binding Studies will be monitored to ensure high quality 	<ul style="list-style-type: none"> Post-authorisation surveillance will be risk proportionate and robust High-quality information on the benefits and risks of medicines will be generated post-authorisation and the results shared
Effectiveness of risk minimisation	<ul style="list-style-type: none"> Monitoring of effectiveness is a new legal obligation for industry and regulators 	<ul style="list-style-type: none"> Specific studies will be done to ensure understanding of safety messages This will change prescribing and dispensing behaviour of health professionals ADRs will be reduced
Periodic Safety Update Report (PSUR)	<ul style="list-style-type: none"> Content changes to Benefit Risk Evaluation Report No routine reports for generic products; timing of submission will be risk proportionate The EMA has published a legally binding list of birth dates and submission dates Eventually, the EMA will process all reports for the EU and all assessments will come through EMA Committees There will be binding/legal outcomes, e.g. variation, suspension, revocation 	<ul style="list-style-type: none"> Benefits and risks are re-examined regularly post-authorisation Negative assessments will change rapidly to warnings Opportunity for international harmonisation between the EU, Japan, and the USA
Scientific committee	<ul style="list-style-type: none"> Formation of the Pharmacovigilance Risk Assessment Committee (PRAC) All key safety issues will pass through this committee 	<ul style="list-style-type: none"> High-quality benefit–risk assessment Legally binding outputs for product reviews Fast, efficient updates to all product information
Transparency and communication	<ul style="list-style-type: none"> Major increase in publically available documents Public hearings at the EMA EMA communication coordination for nationally authorised products EU and national medicines web-portals that will include agendas, minutes, recommendations, and opinions Companies to keep product information up-to-date with the web-portal 	<ul style="list-style-type: none"> Increased and improved information on the benefits and risks of medicines Expeditious information on new safety issues, new advice, and product information updates Coordination of information between Member States
Fees charged for pharmacovigilance	<ul style="list-style-type: none"> New fees will be charged to industry (European Commission consultation recently closed and legal proposal awaited) 	<ul style="list-style-type: none"> Adequate resources should be available to ensure robust public health protection

link for all members of the team, manage the review process, advise on data presentation, and ensure compliance with guidelines, ultimately facilitating the aim of ensuring patient safety.

The Medicines and Healthcare Products Regulatory Agency describes risk minimisation activities for an MAH as ‘ensuring that it constantly monitors the risks of its medicines in compliance with relevant legislation and reports the results of this, as required, to appropriate Competent Authorities. Taking all appropriate action to minimise the risk of the medicine and maximise the benefits, including ensuring the accuracy of all information produced by the company in relation to its medicines, and actively updating and communicating it when new information becomes available’.²⁵ The strategic medical writer has a significant responsibility in ensuring accuracy of information and compliance with the regulations, as well as data interpretation and project management. A problem frequently encountered in the production of post-authorisation documents is the late arrival of essential data, or incorrect data (i.e. data that does not entirely encapsulate what is required in a particular section of the document), which puts extreme pressure on the team to meet the submission deadline. Through collaboration, support, and coordination with the team, the strategic medical writer can pre-empt this by producing a list of data required and the time scales involved as far in advance as possible. Then, through regular communication with the different departments and team members involved, the medical writer can check the progress of data production, thereby reducing the likelihood of late or incorrect data.

The RMP consists of seven parts and the safety specification section is subdivided into eight modules. The new requirements have presented a challenge for the industry in preparing a superior document that incorporates all of the required legislation.²⁶⁻²⁹ The strategic medical writer can help with this challenge by advising on templates and ensuring that the chosen template meets the required legislation.

The RMP assesses the product in the context of benefit–risk analysis in order to prevent or minimise the medicine’s risk in patients. Producing a RMP requires the input of different specialists (e.g. pharmacologists, clinical research physicians, pharmacovigilance experts, and toxicologists). The strategic medical writer’s role includes coordination of the team and management of the review cycles. This includes ensuring that the correct data is received on time, and that the specialists input is

received, reviewed, and included in the document appropriately.

Periodic Safety Update Report

A PSUR (formerly known as the PBRER) is a document used for post-authorisation evaluation of a product at defined time points. The document provides a concise, critical analysis of the medicine. It includes a summary of the benefits and risks, new or emerging information on benefits and risks, and the results of all studies of both authorised and unauthorised uses. Cumulative data from previous reports are also incorporated in the benefit–risk evaluation. The legal requirements for submission of PSURs are established in Regulation (EC) No 726/2004, and Directive 2001/83/EC, and in the Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities, provided for in Regulation (EC) No 726/2004, and Directive 2001/83/EC. The new required format of the PSUR for the EU is based on the PBRER described in ICH-E2C (R2) and replaces the format previously described in ICH-E2C (R1). PSURs provide an opportunity for the MAHs to review the safety profile of their products and ensure the summary of product characteristics and package leaflets are up-to-date. Due to the extent of the changes to the format of the PSUR, significant changes are being made to production, review, and assessment processes by the MAHs.³⁰⁻³⁴ The new format PSUR includes larger and more diverse populations than pre-authorisation documentation and requires the inclusion of a larger amount of data due to the required cumulative analysis and benefit risk evaluation. The strategic medical writer can assist the MAH by being involved at the very beginning of the process, advising on the problems that may arise, such as late data or essential information not being available at the required time, and the impact this has on the very tight timelines.

The new format PSUR is intended to be a common standard for periodic benefit–risk evaluation of marketed products³⁵ and is believed by regulators to meet the national and regional requirements for periodic safety reporting. The objective of the new format PSUR is to provide a critical analysis of new or emerging post-authorisation information on the benefits and risks of a medicine presenting an overall benefit–risk profile that includes cumulative information. The evaluation of benefit is a new facet of this document and unless the safety or benefit–risk profile has changed during the reporting period a concise discussion of benefit is usually sufficient. In the context of efficacy and effectiveness, the new format PSUR

must contain the evaluation of the medicine from the International Birth Date, include relevant new safety information and cumulative knowledge, and focus on new information. It should provide information on all approved indications, dosage forms, and regimens for the active substance. The full ICH E2C (R2) guideline specifies the required format for new format PSURs including table of contents and section numbering, and Section 3 of the guideline gives specific guidance on content.^{36,37} The strategic medical writer can also add value by advising on interpreting the guidelines to produce the template and suggesting the best format to present data.

Post Authorisation Safety Study

A PASS is any study relating to an authorised product that quantifies potential or identified risks, evaluates risks in populations where there is limited or missing safety information, provides evidence relating to the absence of risks, confirms the safety profile of the product, or measures the effectiveness of risk management measures (Directive Art 1 [15]). A PASS may be a clinical trial or a non-interventional study. A non-interventional study should meet the requirements of Volume 10 of The Rules Governing Medicinal Products in the European Union.³⁸ The purpose of a non-interventional PASS is to generate data of clinical or public health importance. If a PASS is a clinical trial, Directive 2001/20/EC details the legal obligations relating to the implementation of good clinical practice in the conduct of clinical trials.³⁸ Companies are required to provide a written study protocol before commencement of the study (details of the format and content are presented in Module VIII of the guideline on GVP³⁹). Pharmacovigilance data and new information generated should be monitored and the benefit-risk balance considered. Information from the PASS should be included in PSUR and RMP updates. The final study report should be submitted as soon as possible after finalisation and within 12 months of the end of data collection, and should include a publicly available abstract (details of the format and content are presented in Module VIII of the guideline on GVP³⁹). For the medical writer, this is where pre-authorisation meets post-authorisation: the skills required are similar to those needed for the production of a pre-authorisation clinical study report.⁴⁰

Conclusion

The strengthening of post-authorisation legislation has instigated documents with new and improved formats. The focus has changed to include a much

stronger assessment of the benefit-risk profile of the product, the aim being to improve patient safety and avoid disastrous events like those seen with thalidomide. To this process the strategic medical writer contributes document expertise, scientific expertise, writing skills, and project leadership²² through effective communication. In addition, the strategic medical writer provides an invaluable central link in the team in the development of post-authorisation documents by anticipating problems, managing the review process, advising on data presentation, and ensuring compliance with guidelines. This results in the production of high-quality documents, ensures a smooth submission process, facilitates the strengthening of the pharmacovigilance system, and ultimately contributes to patient safety.

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