Risk management

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The thalidomide tragedy of the early 1960s cost several thousand lives, but it ultimately led to changes that will undoubtedly save many thousands more: it triggered a chain of events involving the WHO and the ICH that resulted in the pharmacovigilance systems we have today.

A key aspect of pharmacovigilance – the safety monitoring of drugs after their licensing – is risk management, which aims to better understand the benefit-risk profiles of drugs and minimise their risks to patients. A rapidly evolving area, risk management is the theme of both this issue of *Medical Writing* and the 3rd EMWA Symposium in Dublin.

In December 2008 the European Commission unveiled the so-called 'EU Pharma Package', a set of proposals to give EU citizens better access to information on medicines and better protection from the harms caused by genuine and fake medicines. This package was followed by new pharmacovigilance legislation – *Directive 2010/84/EU* and *Regulation (EU) 1235/2010* – which came into force in July 2012, and a revised good pharmacovigilance practices (GVP) guideline from the EMA, published in April 2014: *Module V – Risk management systems (Rev 1)*.

Writing in this issue of *Medical Writing*, **Tiziana von Bruchhausen** and **Kerstin Prechtel** explore how these recent changes have affected safety medical writing, increasing document complexity and helping to create a new role: the pharmacovigilance medical writer. They identify some of the personal qualities pharmacovigilance writers require and outline the processes by which they can prepare Risk Management Plans (RMPs) for different purposes.

In Europe, an RMP must be submitted to the EMA with each new marketing authorisation application. Since July 2012, the EMA's RMP has had a modular format. **Sandra Götsch** guides us through its seven parts (I–VII) and eight modules (SI–SVIII), providing insights, tips, and – for those of us who are new to RMPs – reassurance!

RMPs are further covered in a feature article by **Lesley Wise**, who describes how the risk management of approved medicines has seen an increasing focus on continued benefit-risk activities throughout a medicine's lifecycle. Lesley examines the historical background to benefit-risk assessment, changes to the content and format of RMPs in the EMA's revised GVP guideline (see above), and the new ICH standard for periodic benefit-risk evaluation: the Periodic Benefit-Risk Evaluation Report (PBRER).

Looking to the future (perhaps the not-so-distant future), **Massoud Toussi**, **Lisa Chamberlain James**, and **Alasdair Breckenridge** explore the possible role of social media in adverse event (AE) reporting. They explain the value of AE data from social media and highlight technological and other developments that are needed for such data to be properly captured and used, potentially revolutionising pharma's pharmacovigilance activities.

The Geoff Hall Scholarship winners

Are medical writers ghostwriters?

In this issue, we also announce the winners of the Geoff Hall Scholarships, which are annual scholarships in honour of a former EMWA president. They are awarded to new medical writers on the basis of an essay competition. This year's theme was 'Are medical writers ghostwriters?' The winners are **Andreas Sakka** and **Nicholas Churton**. Their excellent essays give us newcomers' views about this controversial topic.

Reaching out to non-native English-speaking medical writers

Non-native English-speaking medical writers are an important but perhaps underserved part of our association. Much of this has to do with English being the *lingua franca* of medical writing and

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therefore EMWA, but some medical writers write in their own language or at least translate to and from their own language. To reach out to these non-native English-speaking medical writers, Maria Kołtowska-Häggström started a new section, **Lingua Franca and Beyond**, in the last issue of *Medical Writing*. In this issue's instalment, she invites native English speakers to her section to learn about the work and needs of their non-native English-speaking colleagues. Also in this section, Laura C. Collada Ali, a medical translator living in Italy and a member of EMWA's Executive Committee from 2013 to 2015, writes about the importance of having non-native speakers of English involved in EMWA and the Executive Committee. Laura also brings her fantastic energy to the pages of *Medical Writing* by rekindling **Gained in Translation**, our regular feature dedicated to medical translation. She further contributes her regular **Profiles** section, in which she continues her series of interviews of medical writers and translators from all over Europe.