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An Industry Perspective on the Erice Declaration and Risk Minimisation Plans

The timely commentary on the Erice declaration[1] prompts us to write. One prerequisite for the aims of the declaration to be achieved is open communication on benefit-risk issues between industry, academia, regulators and health authorities. In addition, new European Medicines Agency (EMEA) guidelines and the US FDA guidance published since Erice, state that pharmaceutical companies should include risk management plans (RMPs) in their applications for marketing authorisation.[2-5] The EMEA will monitor the implementation of such measures and take action if companies fail to meet the requirements. However, it is currently unclear how far the pharmaceutical industry is from these ideals.

We therefore performed a survey of ten companies within the pharmaceutical industry to gauge awareness and preparedness for meeting both these requirements and; hence, indirectly, those of the Erice declaration. Those companies surveyed were asked about how the new guidance might affect the industry in the future (figure 1). Encouragingly, the respondents hoped that the recent FDA and EMEA guidelines will promote improved communication between industry and academic sectors, better prescribing practices, a more cautious approach to drug launch and adoption, opportunities for companies to rethink their product launch strategies and, above all, improved RMPs and safety profiles for medicines.

However, the survey also showed that there were a number of perceived challenges, such as the additional time and effort, skills and experience in developing robust RMPs, which would require investment in building these capabilities. We believe that another consequence of limited skills and resources is that pharmaceutical companies will have to prioritise the RMP products and, in the survey, concern was raised by companies that the pharmaceutical industry may overlook the opportunity to use risk management constructively. A key conclusion from the survey is that the traditional drug safety functions within pharmaceutical companies (pharmacovigilance and regulatory affairs) appear well versed in the EMEA and FDA guidance, whereas sales and marketing functions are less aware.

Other concerns raised include the financial viability of developing RMPs for orphan-indication products because of cost and resource limitations, as

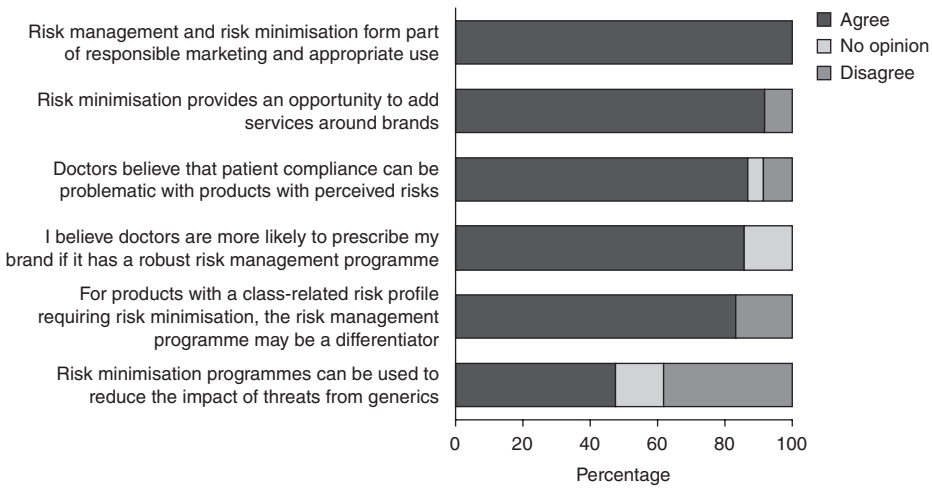

Fig. 1. Responses on how the new guidelines might affect the industry in the future.

well as concern that marketing approvals in general would be delayed because of poor planning of risk management strategies. There is also a risk that additional costs might be passed on to the consumer (with resultant criticism of the industry) or drugs may have to be targeted at narrower populations to ensure that the level of perceived risk is reduced. It was also felt that some drugs may not come to market or have restricted licences, thus allowing continuing usage of less safe drugs already on the market, which paradoxically have less stringent risk planning in place. Respondents predicted that up to a quarter of products on the market might require additional risk minimisation. This may be a low estimate although many products are mature and hence do not warrant excessive interventions. With pipeline products, some participants envisaged that all would require some form of risk minimisation (ranging from educational programmes to relatively complex measures, such as compulsory restricted prescribing), whilst others expected that between 30% and 50% of new drug-licence applications would need specific risk-minimisation measures in place.

Companies also appear to be taking different approaches to risk management including:

- Devolving it to the pharmacovigilance function;
- Developing expertise in risk assessment;
- Outsourcing some work to consultancies;
- Modifying drug safety management from proof of concept to post-launch (through the development of clinical drug safety groups, with separate responsibilities for pharmacovigilance, or reorganising drug safety function that manages safety throughout the development and post-launch lifecycle of the drug).

The Erice declaration states that "The inherent uncertainty of the risks and benefits of drugs needs to be acknowledged and explained". The results of our survey clearly indicate that further work is required within the pharmaceutical industry, particularly outside drug safety and related functions, to increase awareness of this important goal.

Simon Ingate, Deborah Tranter, Anjan Banerjee and *Andrew Hobbs*
Drug Safety and Risk Management Practice, Pope Woodhead and Associates Ltd, Cambridge, UK

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