

# Better awareness and implementation of pharmacovigilance and risk management planning is needed within the European Pharmaceutical Industry

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## Introduction

Pope Woodhead performed a study within the pharmaceutical industry to understand its response to risk management (RM) plans, in accordance with the new EU legislation (EU-RMP) and FDA guidance (RiskMAPs).

Internet surveys and telephone interviews were conducted with a cross-section of relevant sector managers from ten companies to gauge awareness of and preparedness for complying with the new requirements, assess attitudes to these, understand the company's experiences and how EU-RMP and RiskMAPs might affect the industry's future and their relationships with customers.

## Results

### The current regulatory environment

Respondents suggested that the current image of the industry is low because of:

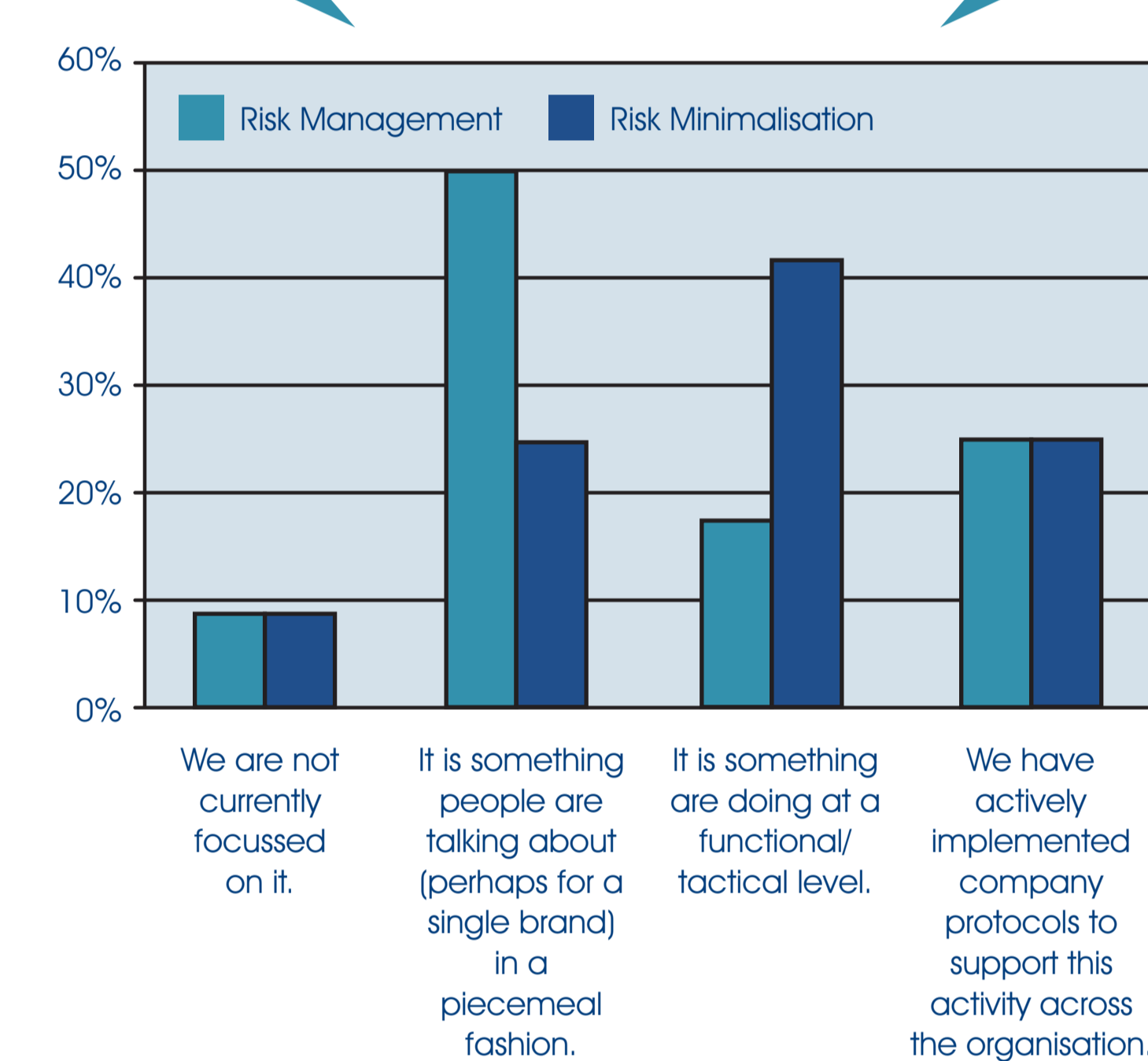
- High profile product withdrawals (attempts to limit liability)
- Underdeveloped risk management practices
- Bad press over clinical trials accidents
- Reactive approaches to pharmacovigilance
- Low level of trust with regulators, prescribers and patients.

### Awareness and "preparedness"

Interviewees were asked to gauge their company's awareness of and "preparedness" for dealing in the new regulatory environment since the introduction of the EU-RMP regulation and FDA RiskMAP guidance.

"We would put RMPs in place for specific sub-sets of patients if we felt they would benefit from additional surveillance or education."

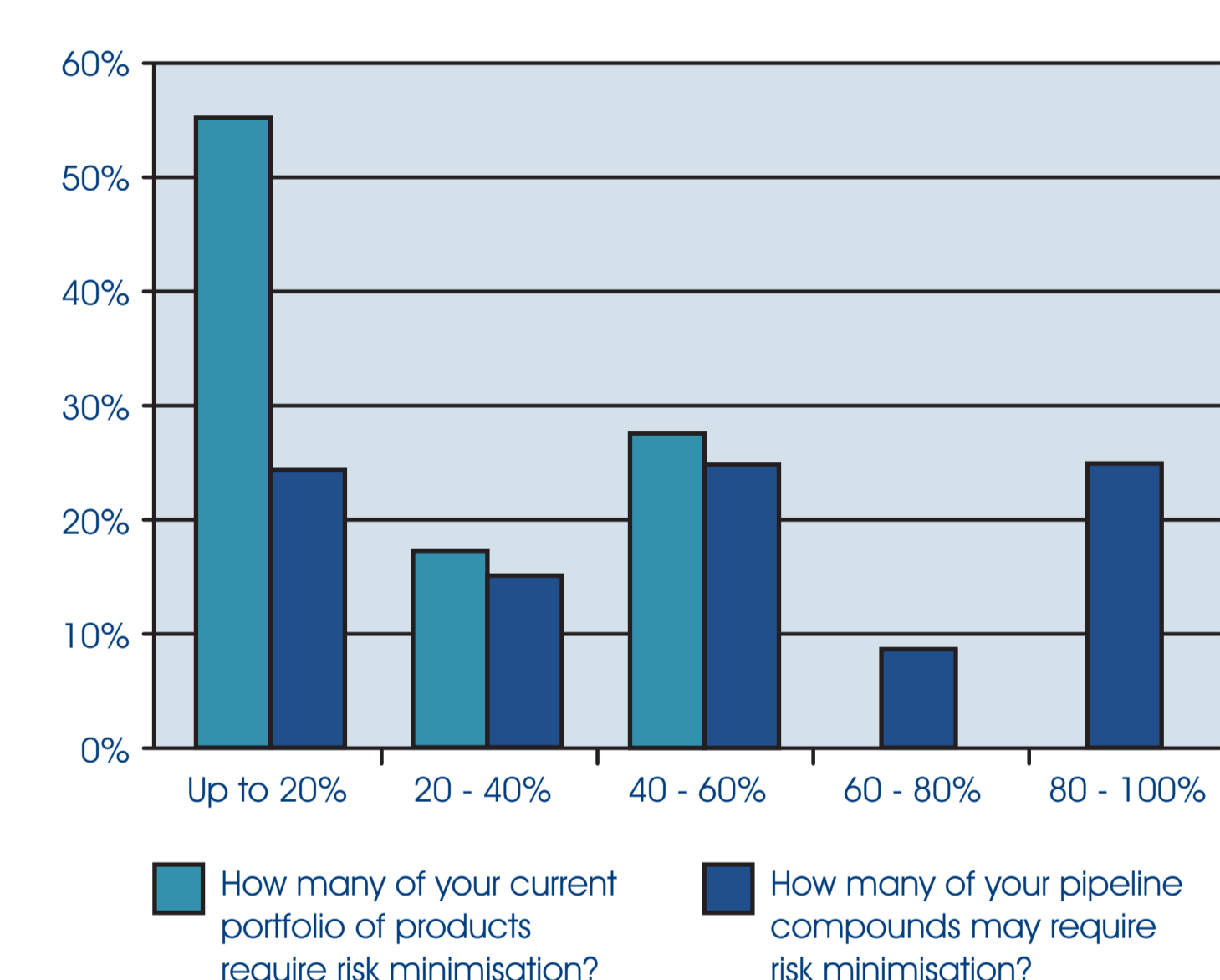
"Unfortunately we have a lot of experience due to a high profile withdrawal a few years ago. We have learnt a lot since then."



- Drug safety related departments are well aware of RiskMAP guidance and EU-RMP regulations but marketers appear to be unaware of the regulation's impact on marketing activities.
- Many companies are beginning to develop approaches towards risk minimisation.
- Risk management is only considered when a brand has a problem, rather than as a routine approach to drug safety.
- Few believe companies are fully prepared (SOPs in place) and <20% are implementing processes at a functional level.

### A "Safety-First" mindset is developing

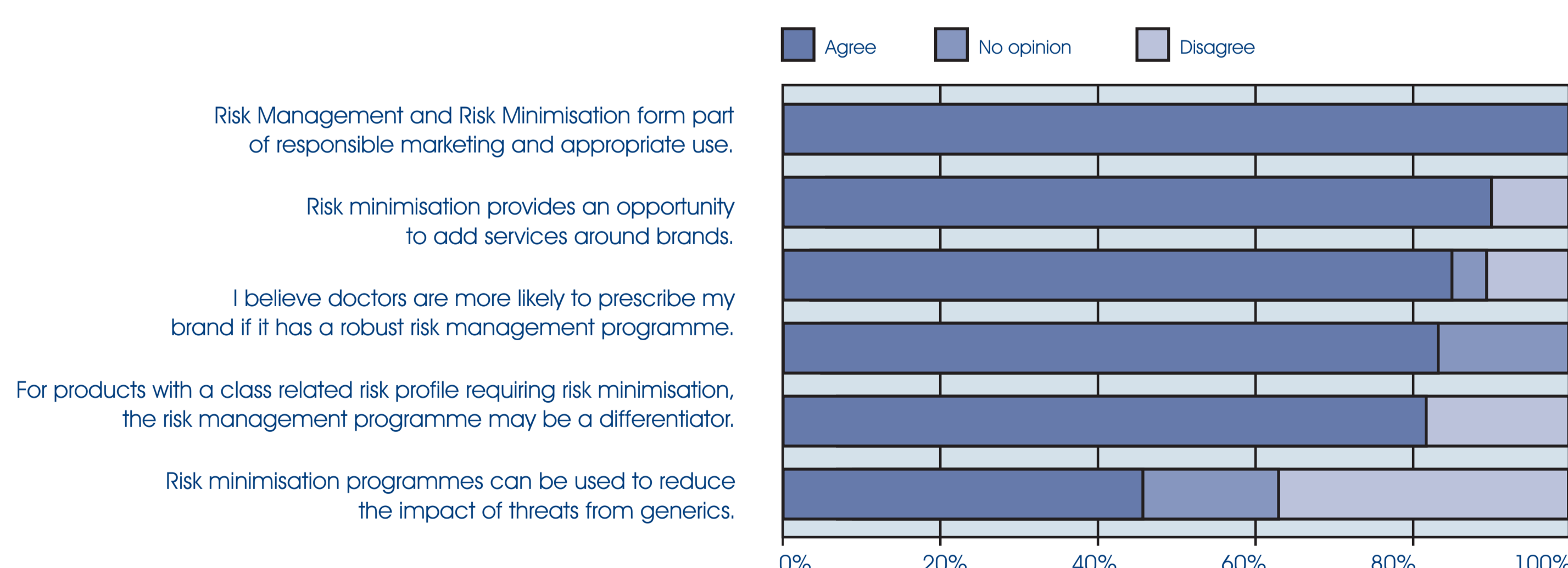
Respondents were asked to estimate the numbers of marketed and development products that might benefit from risk minimisation interventions.



- Estimates of the percentage of pipeline products requiring risk minimisation varied (depending somewhat on the level of innovation associated with pipeline compounds).
- Companies are unlikely to look at risks associated with currently marketed (mature) brands.
- Sales and marketing should focus on the education of prescribers (concerning the appropriate selection of patients) and patients (about the safe use of medicines).
- Sales force training needs to include risks and benefits.

### Safety-First presents opportunities for the industry to improve its act

Respondents were asked to express their opinions on the utility of potential opportunities which risk management provide.

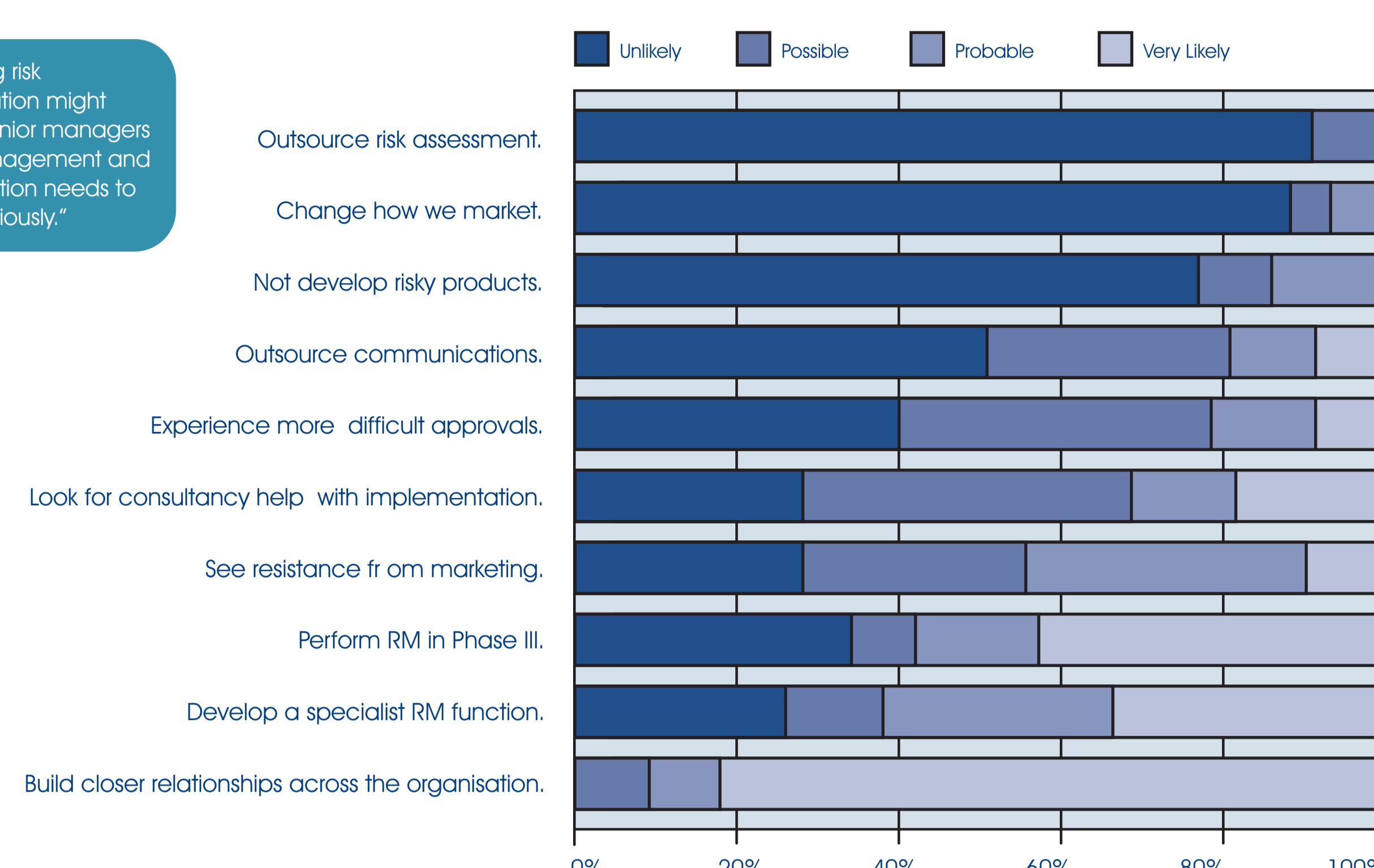


- Risk management is responsible marketing.
- RM programmes provide companies with an opportunity to add services around the brand (predominantly communications vehicles, appropriate use education for healthcare professionals, screening tools and patient education).
- Doctors will trust robust RM programmes.
- RM programmes for class related risks could help differentiate your brand and generate brand loyalty (quality and level of service elements are important).

## Development of Risk Management Strategies

Interviewees provided their opinions on how their companies may react to the challenges presented by a safety-first industry mindset, what organisational changes would be needed and what gaps in processes, skills and resources exist.

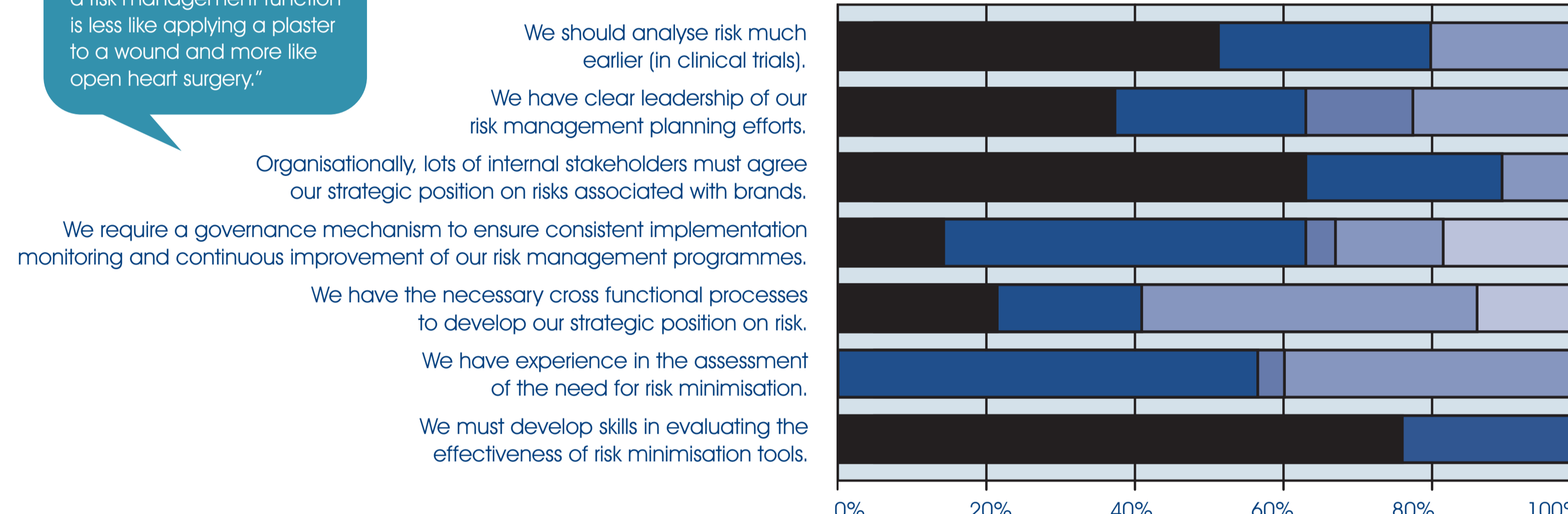
"Outsourcing risk communication might convince senior managers that risk management and risk minimization needs to be taken seriously."



- Fragile products may be harder to register (or with a early risk assessments such products could be failed earlier in their development) but companies would still develop and market "risky" products especially if risk management allows the benefit/risk profile to be improved.
- Marketing will not change substantially (except for the introduction of clearer risk /benefit language in materials). Marketing may initially resist this change.
- Identification of risks will remain the remit of the clinical team.
- Specialist risk management functions could be developed in-house.
- Guidance with respect to strategic planning for pharmacovigilance, phase IV study design, risk management and negotiation with regulatory bodies may be sought externally.
- Internal and external communication and closer relations between stakeholders is essential to ensure the success of safety-first approaches to drug marketing.

## Organisational impact of Risk Management

"In my experience, building a risk management function is less like applying a plaster to a wound and more like open heart surgery."



Key steps in successful implementation of risk management include:

- Clear project leadership and senior level support of initiatives.
- Involvement of all critical stakeholders from across the organization.
- Governance mechanisms to manage programme design, implementation, evaluation and ongoing program improvement.
- Development of necessary cross-functional processes.
- Organisations need to improve their risk identification, planning measures and evaluation of the effectiveness of post marketing risk management

New resources and skills-sets required include:

- Project managers (with scientific and commercial awareness)
  - Epidemiologists
- There will be fewer requirements for statisticians and pure scientists.

Who should be involved in planning/implementing risk management?

- Pharmacovigilance
- Regulatory Affairs
- Clinical Drug Safety
- Marketing
- Product Clinical Team

Interviewees suggested that drug safety personnel should provide project leadership.

## Perceived benefits of a Safety-First approach to drug development and marketing

Respondents believe that a safety-first approach to drug marketing should:

- Improve safety profiles (through appropriate use) and improved case reporting
- Raise the profile of "grown-up" proactive pharmacovigilance resulting in; more measured approaches to population management, better understanding of real life benefit/risk profiles and assisting in the negotiation with regulators to introduce pragmatic post-marketing surveillance focused on the provision of important missing information.
- Encourage companies to take a more cautious approach to launching products and reduce the risk of high profile withdrawals through improved dialogue with regulators.
- Improve the industry's image with key stakeholder groups through; education of prescribers about a drug's risk/benefit profile, providing appropriate use guidelines leading to improved prescribing, and balanced external communications for prescribers, pharmacists, patients and regulatory bodies.

## Conclusions

1. A safety-first approach to developing, registering and marketing pharmaceuticals is not the exclusive remit of Drug Safety - it involves all functions.
2. To do this effectively, global governance mechanisms need to be established and the impact on local implementation needs to be considered.
3. Risk assessment as well as risk management planning and implementation needs to be integrated across the drug development and marketing processes.
4. Broad project management and business focused skills in marketing, drug safety and pharmacovigilance have to be developed.
5. Integrated RM will help to build trust with patients, prescribers, regulators and other key stakeholders.



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