



**FACULTY OF  
PHARMACEUTICAL MEDICINE  
OF THE ROYAL COLLEGES OF PHYSICIANS  
OF THE UNITED KINGDOM**

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**Faculty of Pharmaceutical Medicine's Response to the Department of Health's  
Consultation on the Responsible Officer Regulations and Guidance (August 2009)**

**Introduction**

We welcome recognition of the Faculty of Pharmaceutical Medicine as a designated body however, because its members are employed outside the NHS, the implication of the responsible officer Regulations and Guidance for the Faculty will need further discussion with the Department of Health.

The Faculty of Pharmaceutical Medicine as a designated body will not cover all pharmaceutical physicians with a licence to practise particularly those working within larger pharmaceutical companies. Additional consultation will be required to ensure that these doctors are appropriately covered under the Regulations.

The Faculty's response to the individual questions must be read in the light of need for further consultation.

**Q1. Do you agree that Regulation 3 designates all those organisations that need to have a responsible officer?**

No.

**Q2. If you answered NO to Q1 which other organisations should be designated?**

The regulation will not apply to a substantial number of pharmaceutical physicians. There may be a number of organisations who employ pharmaceutical physicians who may want to be designated (e.g. pharmaceutical companies).

**Q3. Do you think Regulation 5 provides sufficient safeguards in the event of a conflict of interest arising? If not, please explain what further measures should be considered.**

Yes.

**Q4. Do you agree that Regulation 6 should require responsible officers to have a licence to practise?**

Yes.

**Q5. In circumstances where the responsible officer acts for another body, are additional criteria to those in Regulation 7 needed?**

No.

**Q6. Are the functions set out in Regulation 9, relating to the evaluation of a doctor's fitness to practise, appropriate?**

Yes.

**Q7. If you think there are other functions that should be specified, please explain what they are.**

No comment.

**Q8. Do you agree that Regulation 10(1) sets out the appropriate connections for doctors?**

Partly. Different arrangements will need to be put in place for pharmaceutical medicine.

**Q9. Do you think Regulation 10(2) enables doctors in designated organisations to be linked to an appropriate responsible officer regardless of their working pattern?**

Yes. The Faculty of Pharmaceutical would suggest that regulation 10(2)(b)(i) is amended to substitute "clinical practice" with "medical work" or, if not considered appropriate, that both terms are used. The term "medical work" should be used throughout the Regulation to recognise that not all work performed by doctors with a licence to practise will be clinical and involving patients. This is particularly the case for pharmaceutical physicians but also for a large number of other doctors who will wish to have a licence to practise.

**Q10. If the answer to either Q8 or Q9 is NO explain.**

No comment.

**Q11. In particular, do you think there are any other alternatives to using the doctor's registered address as a final report to decide?**

No comment.

**Q12. Please comment on the appropriateness of the system set out in Regulation 11 to manage the conduct and performance of responsible officers?**

There needs to be further discussion on this. For pharmaceutical medicine it may be more appropriate for the ROs of designated organisations to have an alternative RO to one provided by the local SHA.

**Q13 Do you agree that the additional functions of a responsible officer set out in Regulation 16 are appropriate?**

These may be two broad for ROs with responsibility outside the NHS where the RO may not be an employee of the organisation. Under 16(2)(b), the Faculty of Pharmaceutical Medicine RO may be acting as RO to pharmaceutical physicians within small companies and may not have rights of entry into that company's HR records. Further discussion on this with the Department of Health is needed.

**Q14. If you think there are other functions that should be specified please explain what they are.**

No comment.

**Q15. Please comment on the extent to which regulations 12-14 and 17-19 achieve the policy objectives set out in the previous consultation paper on the role of the responsible officer.**

No comment.

**Q16. Please comment on the content, structure, layout and 'useability' of the draft guidance. Comments on the guidance can be submitted either as track changes or clearly annotated with paragraph numbers.**

The draft guidance is useable, but inconsistencies between the Regulations and the Guidance must be rectified. For example, Regulation 10(1) appears to indicate that pharmaceutical physicians will be able to have a prescribed connection to a Faculty of Pharmaceutical Medicine RO whilst Guidance (3.32) indicates that the requirements for doctors who work in research companies have yet to be addressed.

Faculty of Pharmaceutical Medicine  
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