

Response from The Faculty of Pharmaceutical Medicine

Challenges and Priorities for the MHRA - Consultation

Thank you for inviting the Faculty of Pharmaceutical Medicine to comment on this consultation. Representatives of the Faculty have reviewed the document and would like to congratulate the MHRA on producing such a clear statement of its proposed strategies for the coming years and for explaining the background and context of the challenges that the Agency faces. The content of the document will be accessible to a wide range of your stakeholders including, very importantly, those without any previous knowledge or experience of the regulatory environment.

As a registered charity which exists for the benefit of the public and patients, the Faculty shares many of the same objectives as the MHRA and it was pleased to observe that the MHRA's role in safeguarding public health was emphasised throughout the document. The Faculty supports strategies such as the development of a lifecycle approach to regulation and those that will target the problem of counterfeit medicines. The Faculty encourages the continuation of the debate around future models for medicines development and regulation. The proposed move to earlier, conditional licensing of medicines is an interesting concept which may, amongst other benefits, enable the earlier detection of unexpected adverse events.

The consultation document was clearly intended to provide a public statement of the MHRA's top-level strategy that the Agency will now be planning to develop into specific actions for the years ahead. The Faculty would welcome any opportunities to comment on this more detailed work and to explore any opportunities for collaboration that arise.

30 October 2007