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## **Faculty of Pharmaceutical Medicine Response to MLX 359 Consultation on the European Commission's Legislative Proposal to Strengthen Patient Safety ('Pharmacovigilance')**

The Faculty of Pharmaceutical Medicine (FPM) welcomes the opportunity to comment on Public consultation (MLX 359): *Consultation on the European Commission's legislative proposal to strengthen patient safety (pharmacovigilance)*.

The FPM is a registered charity which exists to advance the science and practice of pharmaceutical medicine for the benefit of the public. The FPM agrees with the stated intention of strengthening and rationalising the EU systems for maintaining and taking action on any safety issues. The FPM is in support of proposals to reduce duplication in this area providing these do not compromise patient safety.

The FPM is broadly supportive of the MHRA's intended position but recommends that the following points are also considered for incorporation in the final response.

### **Issue 2 – ADR reporting and EU wide ADR database (EudraVigilance)**

The FPM notes that the MHRA is supportive of the overall aims of the proposal provided that certain conditions are met. The FPM recommends that a clear timeframe be set for achieving these in order that duplication is minimised, as stated in the proposals.

### **Issue 3 – Product Information**

The FPM recommends that the final format of the SmPC and PIL should ensure that essential information is presented clearly to ensure that readers can locate it without difficulty.

### **Issue 4 – Periodic Safety Update Reporting**

The FPM recommends that clarification is obtained to ensure that the proposals also apply to bio-similars and other generic products.

### **Issue 5 – Risk Management System**

The FPM recommends that the Risk Management System does not overlook the fact that new and emerging risks can arise in association with established products. The FPM also recommends that it is essential that the proposed national medicines safety web-portals can be comprehended by the public and other users.

1 September 2009