

MLX 350 FPM RESPONSE

Q1. Do you agree that the proposal provides sufficient clarification in law of the extent of the obligations on marketing authorization holders to report pharmacovigilance information?

The Faculty fully supports the proposals but clarity is required on two points.

- a) The use of the word 'promptly'. This is open to interpretation by different parties and timelines should be specific. With the possibility of a two-year prison sentence as a penalty it seems preferable to have a timetable that cannot be interpreted differently by the regulator and the applicant.
- b) There is also a need for clarity on the separate or joint responsibilities of individual and employer in respect of offences committed by the Qualified Person for Pharmacovigilance (QPPV) role or by the Marketing Authorization Holder (MAH) in failure to support the QPPV role, whether in-house or contract provision of QPPV is used. There appears to be confusion between sections 10 a-d, 10A2c and 15.1. Clarity on where responsibility lies is critical for QPPVs in ensuring that they do all they can to avoid an offence being committed by informing the MAH of its responsibilities and that they, or their employer, provide(s) for professional indemnity insurance in the event that, despite their best efforts, they are prosecuted

Q2. Is there a need for further guidance for industry on compliance with the proposed regulations?

Yes. See comments to Q1.