



## **ABPI Response to the draft comitology text for consultation: Revision of the Variations Regulations**

The Association of the British Pharmaceutical Industry (ABPI) is the trade association for more than 75 companies in the UK producing prescription medicines. Its member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the National Health Service (NHS). The ABPI also represents companies engaged in the research and/or development of medicines for human use. In addition, its general affiliate membership is for all other organisations with an interest in the pharmaceutical industry.

The ABPI welcomes the opportunity to comment on the European Commission's draft proposal for a Commission Regulation concerning examination of amendments to the terms of marketing authorisation for medicinal products for human use and veterinary medicinal products.

The ABPI fully supports the European Federation of Pharmaceutical Industries and Associations' (EFPIA) response to this consultation and our member companies have contributed comments via EFPIA.

The ABPI supports the principles of Better Regulation and, as such, our member companies have participated in the MHRA's Better Regulation of Medicines Initiative (BROMI) pilots in the UK. However, we must confirm that this support is conditional on the fact that the UK regulatory authority supports the review of the Variations Regulations, including the comitology text, and does not endeavour to add an additional level of regulation, unique to the UK, via any BROMI projects.

We look forward to further involvement in discussions on the review of the Variations Regulations via our colleagues at EFPIA.

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