

**From:** Fiona Guy [Fiona.Guy@biogenidec.com]  
**Sent:** 08 April 2008 09:01  
**To:** NARHI Ulla (ENTR)  
**Cc:** Fran Brewer  
**Subject:** Comments on Legal Proposal on Information to Patients

Dear Sir/Madam

Please find below comments from Biogen Idec on the Legal Proposal on Information to Patients.

Biogen Idec would support the proposal to increase the amount of information available to patients and to ensure that this is harmonized across Member States. We agree that patients are becoming more empowered and proactive regarding treatment options and information varies from country to country. However, under the new proposal we do not believe that "unnecessary bureaucracy" will be avoided. Indeed the proposal for a three tier structure for monitoring will, in our view, only add to the bureaucracy. Biogen Idec think that industry self-regulation, similar to the current situation, would be more appropriate if such a proposal were to progress.

Providing rules that "harmonise practices on information provisions to patients in Member States" would be welcomed however it remains very unclear how provision of information, particularly through the mediums of TV and radio, would not be classified as advertising if the information is coming from the marketing authorisation holder. Advertising is any activity designed to promote the prescription, supply, sale or consumption of medicinal products. If the marketing authorisation holder were to proactively communicate objective, unbiased, information (consistent with the SmPC) on its products in public media it could be seen as advertising since this could prompt a patient to request the product from their physician. Harmonisation may be further complicated by the fact that each Member State would have a National co-regulatory body and would adopt separate codes of conduct for each Member State. One central European code of conduct would be preferable.

Please do not hesitate to contact me if you require clarification on the above points.

Yours faithfully

Fiona Guy

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