Dear Sir/Madam,

Focus Pharmaceuticals, as an SME company, have the following comments on the proposed changes to the Variation Guidelines (No 1234/2008).

**Code B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product.**

**Sub section b) Replacement or addition of a manufacturer responsible for importation/batch release**

**2. including batch control/testing**

The proposal is to amend the variation for the above change from a Type $IA_{IN}$ to a Type II.

We, Focus Pharmaceuticals Ltd, are a small company, registered as an SME under European Commission rules, who sub-contract all manufacturing and batch release activities across our range of products. In order for us to remain competitive it is important that we have flexibility in terms of the manufacturers on our MAs. For this reason we often need to use this variation code, among a grouping of variations, under a Type Ib grouping. We note that the proposal is to take the variation from an administrative to an assessed application. At present the variation code, being administrative, allows us to release product in a timely manner after submission of the variation.

The change of category to a Type II variation will lead to a considerable delay, in release of product to market, when adding a new site for manufacture/release and will mean that product will be held in quarantine, for 6-12 months, prior to approval of the site for release; and thus a loss of earnings for us as a company, together with loss of shelf life for the held batches. This change will have a detrimental effect on our business.

If the EU feels that it is important that some form of an assessment of such a change is necessary, and if all the conditions, as listed in the proposals are met for the variation, would a Type Ib application be more appropriate? Although a Type Ib variation still requires time for assessment, the time to approval is more expedient in terms of being able to release product to market.

Best regards,

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