

# Controversy over change to single final signatory

## *Why was the change introduced?*

Recent changes to the ABPI Code of Practice now mean that promotional material and activities can be certified by a single suitably qualified individual. The change to a single final signatory is intended to streamline the certification process and bring the ABPI Code into line with the EFPIA Code.

**2016 ABPI Code – Clause 14.1 – Certification Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause. This person must be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist. The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.**

However, during the ABPI Code consultation process, neither the Code of Practice Appeal Board nor the PMCPA supported the proposed change from two signatories to one. Furthermore, many companies either did not support the change or supported the change provided there be a risk-based approach.

The ABPI Board felt confident that there are sufficient controls to ensure the quality of materials and activities with one signatory and so the change was incorporated into the 2016 Code.

A particular concern for some companies was that the change would affect compliance and company culture and thus create additional inefficiency, contrary to the intention.

## **What effect will this change have on your organisation & culture?**

### **Will a single final signatory make copy review a more efficient process?**

## *What does this change mean for the medical signatory?*

In many companies the relationship between differing functions in a product team is mutually supportive. However, this may not be so in all organisations and there is a risk that, under the 2016 Code, the final signatory may come under undue pressure to certify material or activities that do not meet the required standard, without the support of a second final signatory.

If the final medical signatory is a physician, and is the unfortunate recipient of a Clause 2 ruling, he or she will be expected to disclose the ruling as part of that year's appraisal. A Clause 2 breach is considered within the scope of an SUI (Significant Untoward Incident) and will feature in the physician's GMC revalidation documentation. Who is going to let that become a risk?

### **Will sole accountability make final signatories more cautious?**

### **Will some decline to be final signatories?**

### **Will final signatories seek alternative strategies for the approval of materials and activities and**

**what could these strategies include?**

*What does this change mean for the product team?*

Whether companies will change their internal policy to include a single final signatory is a matter for internal decision makers that will most likely reflect the culture of the operating company. The ABPI Board noted, via the consultation process, that companies could keep two signatories if they wished to.

Single final signatories may be resistant to sole accountability or unwilling to certify high risk materials or activities, particularly in organisations where they feel that the stakeholders do not have a measured view defining acceptable activities. Conversely, they may feel able to take a more authoritative stance on Certification particularly where the consequences of not doing so may be career limiting.

**What would you like to see?**

**Move to single signatory**

**Retain two signatories**

**Outsourced final signatory?**

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*When will the 2016 ABPI Code come into force?*

The 2016 Code came into force on 1st January 2016 though with a grace period until 30th April 2016.

The 2016 Code can be downloaded [here](#).