**Title**

A survey of three pharmaceutical companies’ resource utilisation in copy review activities and proposals for business process improvement.

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**Introduction**

Promotional and non-promotional materials are highly visible outputs of pharmaceutical companies. They are scrutinised by competitors, agencies and sometimes customers. Penalties for errors can be significant, measured in time, reputation or monetary fines.

Central to nearly all codes and systems are requirements that statements and messages are:

* Consistent with the marketing authorisation
* Accurate and capable of substantiation
* Fair, balanced and up to date

Regional and national differences exist in the regulation of:

* Meetings
* Gifts, fees, hospitality and travel
* External approval requirements
* Dispute resolution

The UK industry body, ABPI, issued a code of conduct in 1958. Its current form is very similar to the European industry EFPI code. Many UK pharmaceutical companies place considerable importance on adherence to the code, with large teams working on the review of materials and activities.

Copy review is a now a significant activity that consumes considerable resources, in the form of time, of some of the most expensive and scientifically able members of staff.

The aims of this study were to

* quantify time taken up by copy review activities in a sample of UK pharmaceutical affiliates medical affairs and commercial functions
* identify the origins and consequences of avoidable re-work
* develop solutions.

We present here the medical affairs results.

**Method**

We developed an online survey with three components:

* Retrospective, quantitative estimates of time taken on copy review and numbers of avoidable iterations
* Ranking the common reasons for avoidable iterations
* Free text responses describing potential solutions

This was sent to 249 staff in three UK pharmaceutical companies in 2013 and 2014.

**Results**

We received 118 usable responses from 249 invitations, a response rate of 47%. 48 responses were from medical affairs and 70 from commercial and other functions.

The proportion of the working week spent on copy review by physicians was a consistent 40%. For medical information, the proportion varied between zero and 65%. Scientific advisors spent 0% to 42% of their time on copy activities.

On average just over 50% of time spent on copy activities went on checking scientific statements and claims. The remainder was spent on concept and planning meetings, commissioning, proof reading, compiling materials. Rounds of scheduled review averaged 2.3.

Estimates of the proportion of jobs requiring avoidable rounds of review ranged between 30 and 50%.

This results in between six and eight additional hours work per week

and raised levels of friction, reported as ‘frequent’ or ‘common’ by 80% in one organization and to a significant level in all three.

Missed deadlines were estimated for around one third of projects.

The three top-ranked reasons for re-work were:

* claims not supported
* references missing or not marked up
* differences of opinion

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| --- | --- | --- | --- |
| Ranked reasons for re-work |  |  |  |
| A | B | C |  |
| 1 | 1 | 2 | Claims not supportable |
| 2 | 2 | 1 | References missing or not marked |
| 3 | 4 | 4 | Difference in opinion in interpreting the Code |
| 6 | 3 | 3 | Spelling and grammar |
| 4 | 5 | 5 | Other technical Code issue |
| 5 | 7 | 6 | Review criteria changed during project |
| 7 | 6 | 7 | Layout or presentation |

Free text proposed solutions from respondents were grouped subjectively into themes. The three most frequent cited proposals were:

* meetings to discuss materials before copy got into the review cycle
* improve the scientific accuracy and spelling of copy before review, so that it is right first time
* insist on consistency between reviewers and between reviews cycles

**Conclusions**

Between one third and one half of the available resource in medical affairs teams in the UK is taken up reviewing materials. This varies between organisations depending upon allocation of this activity. Materials are seen multiple times and a significant proportion of iterations are seen again and again. This causes loss of productivity and internal friction between and within departments. Scientists and physicians engaged in review have positive proposals for process improvement, which are consistent across the organisations involved in this piece of work.

This small survey identifies potential best practice. The interventions proposed are not proven to reduce waste in the copy review process. However, it seems likely that pharmaceutical companies could save time and money by adopting some simple solutions aimed at ensuring only good quality, scientifically valid material enters the review cycle, and by defining review standards, roles and responsibilities. Physicians and scientists could be released from desk work to undertake customer facing activities or conduct studies. Hard to fill posts and subsequent reliance on contractors could be reduced.

This activity has crept up on the industry, to the point now that reviewing copy has become an industry within an industry, occupying half of the working lives of hundreds of medical information specialists and pharmaceutical physicians in the UK. This is not mission critical work and is a diversion from the productive and real work of supporting patients and helping customers to understand medicines.

An industry-wide prospective survey is necessary to identify actual resource utilisation in this activity and benchmark best vs worst practice. Process improvement interventions could be formally assessed to measure the savings that can be made.

It is likely that three relatively simple actions could save a lot of time:

* Improve the standards of materials entering the review cycle
* Define and limit responsibilities