

The industry may have hoped the ramping up of the ABPI Code of Practice three years ago would be it, but learning to work within the Code shouldn't preclude trying to shape its future iterations, particularly around digital marketing, says *Adam Fleming*

The last word...?

When the beefed up ABPI Code of Practice was launched in April 2006, many in the industry viewed it as the ultimate in self-regulation. This was as strict as it could get; the last word in self-regulating the marketing and promotion of prescription medicines because it took into account the sea change in the market over the previous decade.

However, the very fact that the 2006 Code had been necessary to reflect these changes should have given us all a clue this would not be the end. In fact, the Code has been updated every two years or so to reflect the constantly evolving market – most recently in 2008.

Those who might wish this process would come to a full stop miss the point. Until the market stops evolving (which is about as likely as Alan Sugar winning Touchy-Feely Boss of the Year), the Code will have to continue to change. Indeed, the future Code will need to include many situations that weren't an issue even as recently as 2006; the relentless and rapid rise of digital communication is just one example where many industry insiders fear to tread lest they become a test case.

Survive it or shape it

So the question becomes: do you simply want to survive the Code, or do you want to play a part in shaping it? What should we as an industry be doing to create a regulatory environment for the future?

Few would argue that the Code has

contributed to an improvement in the reputation of pharma and given some healthcare professionals the confidence to start engaging with the industry for the benefit of patients. And while some may have expressed concern about the stringent changes made in the 2006 Code, the changes were largely supported by the industry.

Indeed, embracing effective self-regulation brings many advantages, not least in avoiding the need for statutory intervention. This point is made strongly by Heather Simmonds, Director of the Prescription Medicines Code of Practice Authority. "We shouldn't lose sight of the good relationship between self-regulation by the industry and the Medicines and Healthcare products Regulatory Authority, which of course is responsible for regulation in this area," she says. "Efficient, stringent and transparent self-regulation is seen by the MHRA as a means of ensuring that regulatory requirements are met. The two systems work well together."

And the figures back that up. Although overall complaints fell 12% in 2008 over the previous year, it is where these complaints are coming from that indicate the industry is seeing the advantage of self-regulation.

"We receive voluntary admissions – whereby a company will write and say, 'we've made an error' – which add merit and substance to the self-regulatory system. It's something that people outside the industry find quite hard to believe,"

Simmonds explains. "The industry also encourages those with concerns about breaches of the Code to consider submitting complaints to the PMCPA."

But that does not mean we can afford to rest on our laurels, marketing compliance expert Steven Gray of Steven Gray Consulting told a recent joint PM Society/PMCPA meeting. "There can't be anybody in the industry who has not at some point been frustrated about what's in the Code of Practice, either because it stops you doing what you want to do, or because it doesn't tell you how to do what you want to do," says Gray. "Effectively, we have a choice: we can negotiate our way around the present Code, or together we have the opportunity to really grasp the nettle and help shape it, by making positive contributions towards what we want to see in it."

Simmonds concurs and says the drive for changes to the Code is coming from within the industry, rather than the PMCPA. "We are all working together to develop and shape the future of the Code as a means of improving the industry's reputation."

'Potentially useful channels such as viral marketing, blogging and social media are either being ignored completely, or at best not being fully utilised'

At a glance

- The 2006 Code of Practice represented a big change – but it was not the end of the evolutionary process, which is still continuing with the 2008 Code
- The Code is well accepted by the industry, which is now playing a more proactive role in driving it forward and making changes
- The Code is silent on some new areas of promotion, for example digital marketing, where there have been few complaints and little detailed information about what companies would like to be able to do
- With another revision coming in 2010, the industry has a great opportunity to shape self-regulation

PM Society's digital marketing recommendations

With so many people still unclear about what can and cannot be done in advertising and communication using digital tools within existing UK and EU regulations, the PM Society has set up a working group to produce a template of industry guidelines.

The Digital Marketing Working Group, comprising representatives from pharma companies and agencies, will discuss a number of topics including:

- Proactive and reactive communication
- Utilising blogs or Twitter
- E-mail permissions – how to secure and store
- Online logistics management sites, eg. meetings
- Webcasts
- RSS and news feeds – provision and sponsorship
- Patient adherence/support programmes

It will operate under the independent umbrella of the PM Society and will present its recommendations to the PMCPA at the end of November 2009.

If you would like to contribute to the PM Society Digital Marketing Working Group please contact Steve Gray at steven@stevengrayconsulting.co.uk

Digital marketing: a grey area

One area where more of this 'joint working' is likely to be seen is in digital marketing. Many companies are fearful of stepping out of line because there is insufficient guidance even in the most recent version of the Code. So potentially useful channels such as viral marketing, blogging and social media are either being ignored completely, or at best not being fully utilised.

Says Simmonds: "The Code applies equally to all forms of communication – be it traditional marketing or e-media. The major difference is that a healthcare professional must have given their prior permission for a company to send them promotional e-material."

However, Gray notes in his book, *The Code Explained* (Communications International Group 2009), that there are still more questions than definitive answers in applying the Code to all forms of e-media.

This situation is made worse by the fact that just about everybody else outside the industry is making their voices heard on these platforms. The Code doesn't make it clear, for example, whether a pharmaceutical company can respond to an inaccurate piece of information posted by a blogger without being in breach, though Simmonds points out that provided blogs comply with the Code they are not prohibited.

"From a medical perspective, the Code is really grey as regards the internet," Felix Jackson, Medical Director at online HCP community MedCrowd, told the PM Society/PMCPA >

THE CODE: FAST FACTS



1 The first edition of the Sales Promotion Practice for Medical Specialities in the United Kingdom, as it was then called, took effect in October 1958. The second edition, by then named the Code of Marketing Practice for Medical Specialities, appeared in December 1962

that time the Committee, and its predecessors, had been chaired by industry executives

3 The Medicines Act 1968 provided the power to make regulations controlling promotion. On 13 May 1977, the Department of Health and Social Security wrote to the ABPI to consult about the proposals for regulations

4 A 'Statement of Intent' was duly implemented through the 1978 edition of the Code of Practice for the control of pharmaceutical advertising.

Notable changes to the Code included the introduction of certification for promotional material and representative's briefing material, etc, prior to use

5 Another significant change came in 1993 when the Prescription Medicines Code of Practice Authority was established to operate at arms length from the ABPI. This answered criticism that it was unsatisfactory for the ABPI to administer its own Code, the implication being that it would

be tempted to manipulate the outcomes of complaints in a manner favourable to the interests of the industry

6 The 2006 edition considerably tightened the rules, but was just one step in its evolution; it was revised again in 2008

7 Consultation is starting for the 2010 edition of the Code; a template of recommendations being drawn up by the PM Society and industry personnel will be presented to the PMCPA by the end of the year

meeting. "The Code isn't clear on this – often it's a bit of guesswork." To general laughter, and with his tongue firmly in his cheek, he added: "What I've tried to do is encourage people to go out there and test stuff, and then we can find the answers." "A lot of questions are around mainstream and emerging technologies," notes Kai Gait, Digital Commerce Marketing Manager at GlaxoSmithKline. "Social media and user-generated content, eg Twitter – indeed everything that is happening on the web – is moving so quickly, and the Code is vague in these areas so this is where we need clarity. Once we have clarity, we can make

bigger steps forward."

But the question remains: is the industry – traditionally risk-averse – prepared to stick its head above the parapet and test the boundaries of the Code, when the Code itself does not specifically refer to these new channels? Surprisingly, despite the industry's obvious concerns, Simmonds says the PMCPA has received few specific enquiries about running a digital campaign within the Code and would welcome more information about what companies would like to do in this area.

However, as Aaron Pond, Senior Account Manager at Aurora points out,

an error has to occur for a judgement to be made, so companies are waiting for others to act before they do. "Digital media is constantly changing and as an industry we are always playing catch-up," he adds. "What is needed is a flexible framework of guidance that can evolve with digital media."

To this end, the PM Society is heading up a working group of agency and industry personnel who will put a template of recommendations to the PMCPA by the end of the year. The authority, for its part, is receptive to the idea.

The red face test

At the end of the day, the litmus test for any self-regulating group is how its activities are interpreted. Just as in the recent expenses scandal your MP might have done everything strictly by the book, but would still be embarrassed to explain it to you as a constituent on your doorstep, a similar 'red face test' has applied to pharma for many years.

Any activity needs to be within the letter of the Code, but if you would feel awkward defending it publicly, then you probably shouldn't be doing it. And that could be an increasingly useful yardstick as pharmaceutical marketing moves into previously uncharted waters.

Consultation about the 2010 revision of the Code is taking place this year. To receive further information about the consultation and to air your views, sign up to the email alerts on the PMCPA website (www.pmcpa.org.uk). **PT**

Adam Fleming is an independent healthcare writer

Steven Gray answers five of industry's most frequently asked e-marketing questions:

Q: Can companies sponsor online discussion groups, and if so how?

A: Yes they can but companies need to be sure that all content complies with the Code, and this is not generally what participants want from discussion forums!

Q: When is a company liable for reporting adverse events that are identified on a site it sponsors?

A: Right now, companies cannot sponsor websites with free text areas, so the question does not arise. This is one of the questions that will have to be resolved if pharma sponsorship of discussion areas is to be allowed.

Q: To what extent is a company liable to report adverse events if it sponsors a blog discussion forum?

A: To an extent, thus depends on what is meant by 'sponsored'. If it is supported by a hands-off grant then, in theory, pharma is not responsible. However, the MHRA position is not completely clear at present.

Q: If a patient praises a company's product in a patient level forum, is

the sponsoring company in breach of direct-to-consumer advertising restrictions?

A: If the pharma company is connected with the forum in any way – yes. Which is one of the many reasons why companies cannot currently sponsor free text discussion areas.

Q: What happens if I am browsing a health related site in my leisure time and I see something inaccurate? Should I correct the mistake and should I declare my affiliation?

A: Right now the best advice is that you should report your concerns within the company (probably to Medical Information). An informed view can then be taken as to whether action is appropriate on safety grounds or to correct a significant inaccuracy. However, the company is unlikely to intervene in all but the most serious instances because there is a risk that the intervention could be seen as promoting the product to the public. Under no circumstances should the employee act on their own because the activity will be regarded as an official company action by the very nature of their employment.