

In response to the latest PMCPA guidance on Digital Communications, the Red Door Communications Group hosted a workshop led by Dr Nick Broughton, Managing Director of pharmaceuticalethics.com attended by colleagues working in marketing and communications in various therapeutic areas.

The objectives of the workshop were to reflect on current practices within the UK pharmaceutical industry and debate ongoing challenges and opportunities.

This report reflects the key discussion points that came out of that workshop. For more information please contact Julia Harries on 020 8392 8040.

Ethics and compliance in digital communication

By Simon Warne

When working in the new world of digital communication, pharmaceutical companies need to work as hard on the ethical as the commercial justification for what they are doing. It is important to put the patient first and balance the justice, autonomy and chance of benefit against the risk of harm. There's always a danger of jumping on the social media bandwagon without thinking things through, but there's an equal chance of doing nothing because companies are paralysed by the current rule-based compliance paradigm. In the future, ethically competent companies will dominate in the digital arena, while rule-based hand-sitters will fail.

To be successful in a digital space, pharmaceutical companies need to have a good ethical understanding. They cannot rely on the rule book.

Ethics and principles are global, and with social networking increasing all the time it is important that companies reflect on the wider picture and assess whether or not to get involved in digital activities.

Competing Tensions

Social media is the use of web-based and interactive technologies to turn communication into interactive dialogue. It's a global phenomenon and it is so cheap to get involved that everyone's taking part – except perhaps the pharmaceutical industry.

This is partly due to a central conflict between the US and Europe over if and how companies should promote themselves and their products to patients. The US is more liberal, in line with the principles of the country's First Amendment – supporting the right of the industry to speak directly to the public, as it must to uphold the concept of free speech enshrined in the constitution. Whereas Europe while wanting patients to have greater access to information, falls short of direct-to-consumer advertising.

Against this backdrop there have been delays in social media guidance for the pharmaceutical industry on both sides of the Atlantic. Something is expected from the US Food and Drug Administration this year while the PMCPA has just delivered guidance in the UK.

In addition, pharmaceutical companies have to cope with European legislation on pharmacovigilance which has created an over-the-top nervousness about adverse event reporting. The European Commission is also pushing for pharma companies to supply more information for patients.

Added to which the Advertising Standards Authority has issued rules on claims made in websites.

It feels as if social media is going in one direction with lack of regulation and freedom of speech, while the pharmaceutical industry and the regulations surrounding it are going in the opposite direction.

PMCPA Guidance

Medicines are highly regulated whereas social media is unregulated or, perhaps more accurately, self-regulated.

The PMCPA has issued guidance on digital activity rather than made Code of Practice changes, as complaints in this area are, to date, very few.

The good thing about the latest PMCPA guidance is it's not too specific. An abundance of specific rules might lead to a reduction in opportunities for pharmaceutical companies and, perhaps paradoxically to some, this may not be in patients' best interests. Also specific rules go out of date very quickly.

The guidance states that pharmaceutical companies can use any method of communicating to any audience provided relevant requirements of the Code are followed. Unlike in the US promoting directly to the public is not allowed.

The PMCPA guidance is clear as to what qualifies as legal 'promotion' - something proactive and directed at healthcare professionals (HCPs) that contains all the required prescribing information.

The PMCPA views FAQ documents on company websites as 'promotional' and therefore expects these pages to be restricted to factual information. This is open to question.

The use of social media to 'increase awareness and encourage engagement about prescription medicines' is seen as promotion, as is using Twitter to communicate study results. If these activities are clearly directed at the wider social media audience not just HCPs, then they are not acceptable.

Pharma companies are responsible for the content of discussion forums on their own or sponsored websites. Pre-moderation is therefore required if companies are to guarantee that all forum content complies with the Code.

It is also important that the intended audience for the digital activity is made clear - this is most effectively done in websites where companies have separate buttons for patients and healthcare professionals, leading them down different viewing paths.


The guidance does not mention digital advisory boards and how to moderate their online discussions - although if these were conducted on password-protected portals to avoid any chance of patients seeing the content presumably they would be acceptable.

The most important thing is that the pharmaceutical industry displays transparency in all its activities, promotional or otherwise.

This particularly applies to grants to third parties for social media sites where the pharma company should stay at arms length from the site's management and content. Pharma companies should not promote these sites unless they are completely Code compliant.

The unanswered question here is whether companies can sponsor third-party sites in disease areas where they produce the single orphan drug treatment.

When it comes to pharmacovigilance the guidance says it is reasonable for pharma companies to monitor adverse effects reporting on sites which they sponsor.



However the PMCPA guidance suggests that pharma companies should leave other information sites such as Wikipedia well alone. 'Correction of material might lead to more challenges as it would be beholden on the company to ensure that everything was correct including statements about competitor products,' it says.

But many working within the industry feel that if something is displayed on Wikipedia which is wrong and could cause patient harm then pharma companies are morally obliged to do something.

Surely there is no reason why pharma should be excluded from this social space provided it is completely transparent, acts ethically and in the patients' interests? Although obviously these provisions are open to subjective interpretation and companies must be prepared to defend what they do.

If links are made to other sites in pharma online resources they must be reputable and there must be a clear rationale for referring to one site in preference to another. PMCPA guidance also says it should be clear to the visitor when they are leaving a company site.

Search Engine Optimisation and metadata can be used to increase the ranking of sites but product sites should not be optimised in general search terms – in other words if a patient searches for cardiovascular disease the first site they read should not be information about a specific cardiovascular product posted by the manufacturer.

Company blogs must comply with the Code and companies should not sponsor blogs where it can be reasonably expected to discuss medicines and their uses as it is impossible to guarantee compliance.

Initial reaction to the latest PMCPA guidance has recorded a verdict of 'underwhelming'. Companies would have preferred to see a list of what they can do, rather than what they can't.

Common Morality in the Digital Space

Social media can be lots of things – it can be cheap, uncontrolled, rapid, profound, kind, cruel, harmful, vapid, powerful, beneficial and accessible. It is vital that before they enter into the digital space pharma companies are aware of the negatives as well as the positives.

Rather than be put off by the area as a method of communication, the industry should be encouraged by the common morality which exists in the public space to quash unreasonable behaviour online and quash prejudicial attitudes that would rather it didn't get involved.

Everyone recognises the basic principles of what's right or wrong to do. As a culture, we know 'good' from 'bad'. This common morality operates very clearly in social media.

The pharma industry has operated for too long thinking its Code is its ethics. When there isn't any Code guidance people flounder and this has led to a demand for rules. Without too many hard and fast rules in the latest PMCPA guidance it is worth exploring new territory with social media.

Keeping common morality front of mind – it's no good finding a solution in the Code if it sits outside what people think is right or wrong.

As social media grows it is vital for the pharma industry to come out of Code dependence and defend its intention. Companies need to think about their values, the PMCPA's values, HCPs' values and patients' values. Safety underpins every clause in the Code – so if by engaging in digital activity companies are seen to be putting patient safety first and respecting patient and HCP autonomy, who is going to argue against them?

Companies cannot afford to hide behind the Code. Not all rules offer protection - as MPs in the UK found out when their expenses were examined.

Many people working within the pharma industry believe that pharmacovigilance is being used as an excuse not to get involved in digital activity.

Some companies fear that an unprecedented number of adverse events may be reported with internal systems unable to cope, but even if this was proved correct, can it be justified ethically as a reason not to engage?

In addition smaller companies may feel they do not have the resources to support digital activities, whether in terms of 24/7 monitoring or pharmacovigilance. However much of this support can be outsourced, allowing smaller companies to compete in the digital space with their larger competitors on a level playing field.

Ethical Principles and Virtuous Intention

The pharmaceutical industry could do worse than operate under the four principles of Principlism developed mainly after the work of Beaumont and Childress in the late '70s. Applied to pharma these encourage companies to exercise:

- respect for autonomy (ie transparency, confidentiality) - if you don't make it clear who you are, you're robbing people of their autonomy
- beneficence – the more good you do for patients the more likely it is to be ethical
- non-maleficence – don't harm anybody
- justice – be fair to people

All companies need to remember that they cannot promote to the public and cannot promote outside the licence of their products.

An activity is promotional of a medicine if the primary intention is to influence opinion to favour that medicine – it's pro-active, from people with something to gain, in control of the message and maximises the positive while minimising the negative.

Creativity, Ethics and Courage

For creative pharma companies who are confident in their ethics and have the courage to do something different social media provides a huge opportunity.

If people are abusive about pharma companies online are those companies going to let it go? Surely they have to be able to address it.

For example, people question their doctor's advice on line. So why not build your own online community to counter balance the negative and inaccurate claims written by external communities?

Likewise it might be in patients' best interests if you pilot forums moderated for factual information and don't get wound up by ugly remarks – forums self-moderate to a degree as reasonable people will always put down unreasonable people.

For a confused pharma industry doing nothing may be as bad as doing the wrong thing. But provided companies chart the ethical decision for doing something – and can answer their critics, social media should not be as daunting.

Dr Nick Broughton
qualified
at Nottingham
University Medical
School and worked
in hospital medicine
and primary care
for seven years
before joining the
pharma industry.



His first role was as a clinical research manager in phase II and III studies at Sanofi Winthrop before moving into a medical adviser role at MSD UK.

The majority of his pharmaceutical career has been at AstraZeneca where he was UK Medical Affairs Manager before becoming UK Head of Medical Affairs and then European Director of Regulatory Affairs.

Nick is co-founder of Pharmaceuticalethics.com which provides audit, education and consultancy services to pharma and allied agencies.