Mind the Gap

The provision of patient-friendly information has been somewhat neglected by the pharmaceutical industry because it is difficult to measure its 'return on investment'. However, this may all be changing…

Lisa Chamberlain James at Trilogy

For many years, patients' sole source of knowledge was their trusted GP, and thus what they recommended, went. As long as pharmaceutical companies could convince prescribers that their drugs were the best to prescribe, they were rewarded with sales. However, the explosion in publicly available information has changed the pharma/prescriber relationship for good. Doctors are now faced with 'informed' patients, who visit them armed with printouts taken from hours surfing the internet. Some 80 per cent of internet users look for health info online, making it the third most popular online pursuit, following email and using a search engine (1).

Furthermore, a survey of 178 cancer listserv users showed that 35 per cent chose the internet as their preferred source of health information – even ahead of their oncologist (2). However, these 'facts' that patients take from the internet are gleaned from a disparate array of sources, from the very general Wikipedia and Google to specialised sites aimed at healthcare professionals. Their quality and authenticity vary as widely as the internet itself. It is little surprise that doctors become exasperated by patients who have self-diagnosed and appear only to demand the course of treatment they have 'chosen'.

In response to this, the Association of the British Pharmaceutical Industry (ABPI) has attempted to protect the public and stem the flow of unregulated information through social media by issuing advice to pharmaceutical companies on appropriate and responsible behaviour. However, it is hard to imagine how regulatory agencies could police everything provided by these companies on the internet (even if they had the power to do so). In addition, a large amount of online information is not from pharmaceutical companies, but from private groups or individuals who are not bound by such advice. This leaves regulators facing an ever increasing tide of often inaccurate and potentially dangerous information aimed at patients, which is not regulated or approved.

Recognising Obstacles

The EMA has responded to this challenge by recognising the importance of patient information in its latest Risk Management Plan (RMP) update (3). The RMP is a complex document, but in brief it sets out what a product is and does, what is known about its safety, and what has been found in clinical trials, along with what has been found once the product is on the market (if applicable). The RMP also outlines all of the safety concerns, the company's pharmacovigilance plan and risk minimisation measures (for example, what the company plans

Table 1: Online use by age of user

Activity	Millennials Ages 18-34	Gen X Ages 35-46	Younger boomers Ages 47-56	Older boomers Ages 57-65	Silent gen Ages 66-74	GI gen Age 75+	All online adults Age 18+
Go online	95 per cent	86 per cent	81 per cent	76 per cent	58 per cent	30 per cent	79 per cent
For the following activities, the youngest and oldest cohorts may differ, but there is less variation between generations overall							
Email	96	94	91	93	90	88	94
Use search engine	92	87	86	87	82	72	87
Look for health info	78	84	80	83	73	69	80
Get news	76	79	76	76	67	54	75
Buy a product	68	66	64	69	59	57	66

Adapted from Pew Research Center's Internet and American Life Project surveys, 2008-2010. Findings for individual activities are based on adult internet users. For survey dates of all activities cited, see the 'Methodology' section at the end of the Generations 2010 report: http://pewinternet.org/reports/2010/generations-2010/methodology/note-on-survey-dates.aspx

to do to monitor safety problems and how it plans to minimise them).

RMPs can be very large, complex documents and require a significant level of medical understanding to be able to navigate them. However, they are of crucial importance in the assessment of any medicine. In recognition of this, the EMA has included a specific annex aimed at patients. It comprises a 'Patient Summary of the RMP' and is intended to explain in lay terms the main points of the plan. This summary, aimed specifically at patients, has been made part of legislation, and so is part of the law.

In doing this, the EMA hopes to provide a patient-friendly document that explains in simplified medical and scientific language the risks that their medicine carries, along with the benefits it can provide. This strategy carries an added bonus. Not only will a repository of regulated and assessed information on medicines be accessible to patients, but by explaining to them clearly what their side-effects might be, and why it is important to take their medicines in the way they are designed to be taken, it is hoped that patient compliance rates will increase. Currently, 50 per cent of people do not take their medications as prescribed, and this is responsible for 10 per cent of all hospitalisations and over 125,000 deaths annually in the cardiovascular area alone (4). Additionally, it is hoped that such transparency will increase patient confidence in the pharmaceutical industry, and reduce the incidence of adverse effects caused by poor communication or misunderstanding of medicines – approximately 10 per cent of adverse drug reactions can be attributed to a communication failure between provider and patient (5).

In 2005, a Medicines and Healthcare Products Regulatory Agency survey that showed that the general public want far more information about their medicines than is currently available. The RMP summary for lay readers will certainly help to address that need if companies can indeed write them in patient-friendly language. The biggest problem with patient-intended documents written by pharmaceutical companies is that they continue to read like regulatory documents, and patients do not always understand the information they receive because it is often written at an excessively high reading level (6). After decades of having healthcare professionals and regulatory assessors as their primary target audience, the skills needed to write for patients are not always easily found in the pharmaceutical industry.

Importance of the Written Word

The need for appropriately written patient information is underlined by the fact that some 1.1 million people in England are functionally illiterate, and around 16 per cent of adults have lower literacy skills than those of an average 11 year old (7). This means that converting complex medical information into a form that can be understood by 'average' adults with no medical training is challenging. This is even more challenging when numeracy is considered – 1.7 million people are functionally innumerate – which is essential for understanding the risks and benefits of drug safety information (7). For example, it is known that people with a lower numeracy level make larger errors in interpreting side-effect risk information.

To ensure that these RMP patient summaries serve their purpose, the industry needs to focus on making sure they communicate at a level that the general public understands. It will be important to use medical writers who are trained to explain complex information to patients in a way that is understandable and easily accessible. It would be a shame to lose the momentum that the EMA is trying to create with these new summaries by continuing to just write a document full of regulatory jargon and hoping it will 'do the job'. If pharmaceutical companies take up the challenge that the EMA has given them, and work with professional communicators to produce documents that truly improve the quality of the patient information being produced, the industry as a whole will benefit. This is a very important step towards closing the gap between pharma/doctor information and patient information, but however difficult, the rewards will certainly be worth the effort.

References

1. Visit: www.pewinternet.org/reports/2011/healthtopics.aspx
2. Tustin N, The role of patient satisfaction in online health information seeking, *J Health Commun* 15(1): pp3-17, 2010
3. Guideline on good pharmacovigilance practices (GVP), Module V – Risk management systems, EMA/838713/2011, issued 20th February 2012
4. Deshmukh PR and Wasankar SW, Medical expert system, *Advances in Medical Informatics* (2), pp10-13, 2012
5. Institute of Medicine, To err is human: building a safer health system (executive summary), Committee of Quality of Healthcare in America, 2000. Visit: www.nap.edu/catalog.php?record_id=9728
6. Davis TC, *Ann Intern Med* 145, pp887-894, Taylor J *et al*, *Eur Respir J* 2005, pp26:57
7. Skills for Life Survey 2003

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