Managing Physician-Industry Relationships

Jan Heybroek examines moves by industry and regulators in the US and Europe to make physician-industry relationships more transparent.

Wherever you turn these days, there seems to be a report on the complex professional relationships that exist between physicians and life sciences industry representatives. Certainly, this generates high interest due to the importance of healthcare to society and because of the many perceived and real conflicts of interest. Notwithstanding several recent and highly publicised cases[1], this is not a new phenomenon. A news archive search on the topic revealed more than 35,000 articles published between 1980 and 2009. Interestingly, the annual volume of articles has remained nearly stable between 1999 and 2009[2]. What has accelerated since 2008 is that stricter laws, regulations, and ethical guidelines for industry representatives and physicians have been adopted in the US and the European Union.

The US and the EU have adopted stricter laws and guidelines for industry reps and doctors since 2008

In the US, investigations by the Office of Inspector General of the Department of Health & Human Services, as well as the Senate Finance Committee, spearheaded by Senator Chuck Grassley (Republican – Iowa), have provided significant impetus for this recent awareness and the redefining of industry interaction with physicians. In fiscal year 2008, the OIG fined medical devices company Zimmer and pharmaceutical manufacturers Merck & Co and Bristol-Myers Squibb a total of $1.2bn, excluding interest, for marketing malpractices, including illegal remunerations of physicians to entice product usage[3].

This trend seems to have some spillover effect in Europe. For instance, the package of reforms the European Commission announced for the pharmaceutical sector in December 2008 for implementation in 2011-2012 include proposals for better management of physician-industry relationships.

Such exposure – financial, legal and PR – has acted as a catalyst for involved parties to seriously review their positions. Given the many stakeholders in healthcare, the different interests and viewpoints, and the speed of change, any review of current regulations is near impossible. This article highlights key recent and pending changes concerning physician-industry relationships in the US and the EU (Table 1), and presents key considerations. Useful resources that can support the updating of policies are listed throughout.

Such exposure has caused a number of stakeholders to seriously review their positions

Myriad rules and regulations

As most industries have evolved their understanding of marketing and influencing customer decisions, so has the life sciences industry. Guidelines and regulations on interactions between industry and physicians have been defined since the 1980s, both in the US and Europe. Many of these regulations are self-monitoring and member-focused, both at international and national levels. These come from groups such as the International Federation of Pharmaceutical Manufacturers and Associations, the Association of the British Pharmaceutical Industry and the Pharmaceutical Research and Manufacturers of America. In the US, professional organisations such as the American Medical Association or the American Academy of Orthopaedic Surgeons, and other institutions, including Yale University and the Cleveland Clinic, are also involved.

Additionally, there are many applicable national and local laws. For instance in the US, several federal statutes are relevant, such as the False Claims Act, anti-kickback statutes and the Civil Monetary Penalties Law[4]. Additionally, the OIG has published guidelines, advisory opinions and fraud alerts that provide further guidance to manufacturers of life science products[5]. An excellent resource is their Program Guidance for Pharmaceutical Manufacturers, published in 2003[6].

As of January 2009, seven US states (California, Massachusetts, Maine, Minnesota, Nevada, Vermont, West Virginia) and the District of Columbia have laws requiring disclosure of physician-industry interactions. Moreover, at least 90 of the 125 Academic Medical Centers in the US have policies in place relevant to interactions with physicians[7].

Seven states currently have laws requiring disclosure of doctor-industry interactions

Complexity of relationships

Table 1 lists some of the more important updates to guidelines and laws affecting industry-physician interactions that have been implemented or announced recently. The information there provides many clues as to the real challenge of managing physician-industry relationships: knowing what is acceptable, appropriate and allowed when and where; and what is not.

Jan Heybroek is president of the Arcas Group, LLC, a strategic life sciences marketing organisation based in Alpharetta, Georgia, US. Email: jan@thearcasgroup.com.

Table 1. Guidelines, codes of practice and laws introduced or modified in the US and Europe

United States	
Physician Payments Sunshine Act of 2008 (S 2029 and HR 5605) – introduced in 2007 and 2008, re-introduced early in 2009	Law intends to require life science companies (drug and medical devices) to report all payments and gifts ($25 and more) made to physicians, with the information stored in national, publicly available database[8]. Fines for noncompliance. Supported by PhRMA and several life science companies, and will act as basis for internal policy revisions. Re-introduced bill further reduces payment threshold for reporting from $500 to $100.
PhRMA updates **Code on Interactions with Healthcare Professionals** – in effect, 1 January 2009	Updated and stricter voluntary code that builds on 2002 PhRMA code. Prohibits distribution of promotional non-educational items (pens, mugs, etc), provision of restaurant meals to physicians by industry representatives, and clarifies positions on other interactions such as continuing medical education, speaking and consulting arrangements, and disclosure requirements[9].
Advanced Medical Technology Association (AdvaMed) Revised and Restated Code of Ethics on Interaction with Health Care Professionals – goes into effect, 1 July 2009	Updated and stricter voluntary code that builds on 2005 AdvaMed code. Prohibits provision of entertainment, recreation and gifts of any type, including non-educational promotional items, and introduces and clarifies guidelines on royalty arrangements with health care providers[10].
AMA launches a comprehensive review of its Code of Ethics – to be released, June 2011	This review will include professional guidelines for the interaction between physicians and industry, and is expected to bolster the current guidelines. These have been in effect since July 2001[11]. Important and relevant guidance was published in 2007 by the AMA's Commission of Ethical and Judicial Affairs particularly pertaining to the medical devices industry, detailing the dealings with industry representatives in clinical settings[12].
Massachusetts Department of Public Health is developing regulation based on Chapter 305, signed into law in August 2008 – goes into effect, 1 July 2009	This regulation will establish a marketing code of conduct for pharmaceutical and medical device companies, requires staff training, appointment of a compliance officer and disclosure of all financial interactions over $50 between industry and healthcare providers. Will likely be the strictest state law in the US when implemented[13].
Cleveland Clinic announces disclosure of business relationships between their physicians and medical industry – in effect, December 2008	Generally viewed as a major step by a leading international research center, other medical research centers in the US and around the world will likely adopt similar policies. The lower limit for public disclosure is currently set at $5,000, though this may change[14].
National Institutes of Health update staff policies on managing conflicts of interest – in effect, 18 June 2008	The NIH policies for its staff in managing conflict of interest are amongst the most prescriptive and restrictive of all guidelines for healthcare professionals. The policies were updated in 2008[15]. At the same time, a number of the NIH collaborative groups have enhanced their guidelines on industry relationships.
Europe	
European Commission Communication on the future of the pharmaceutical sector – presented December 2008, targeted implementation 2011-2012	This document describes a number of legislative and policy initiatives to make progress towards a single and sustainable market in pharmaceuticals. It states the objective of an in-depth monitoring of the functioning of markets in the pharmaceutical sector, which would likely include physician-industry collaborations[16].
UK ABPI implements new code of practice for members – in effect, 1 July 2008	This document strengthens the 2006 code, which was an evolution of the first one introduced in 1958. The updated ABPI code appears the strictest – from industry's perspective – of any of the national codes of conduct in Europe[17].
Association of German Pharmaceutical Industry amends code of practice for its members – May 2008	The updated code provides more detail and guidance on industry interactions with physicians, including invitations to educational meetings, contracted services and gifts. It clarifies certain practices, including promotion, and reinforces the need for transparent, contract-based relationships between industry and healthcare providers[18].
Finland, Italy, the Netherlands and Sweden all update their marketing codes – 2008	These codes include guidelines on physician-industry interactions. The Dutch guidelines are amongst the most prescriptive and restrictive of all, containing specific maximum amounts allowed for physician reimbursement[19].

The Physician Payments Sunshine Act was reintroduced early in 2009

The Massachusetts law will likely be the strictest in the US when it is implemented

The European Commission pharmaceutical sector reforms also target doctor-industry collaborations

The updated German code provides more guidance on invitations to educational meetings and gifts

Not only are the relationships between physicians and industry incredibly complex, physicians often play multiple roles, each with its own set of regulations and expectations (eg clinician, investigator, educator, etc.) Depending on one's own place in the spectrum of healthcare and geography, different rules and regulations apply. There is a limitless range of situations that are so-called "grey areas", which are not covered or where rules and regulations are insufficiently clear.

Additionally, this issue concerns almost all physicians, and therefore must be handled properly. A recent study, published in the *New England Journal of Medicine* in 2007, showed that 94% of all physicians in six therapy areas reported some type of relationship with the pharmaceutical industry[20].

Practical framework

No system will ever be able to address all physician-industry relationships in a comprehensive way. So what is the best approach? The short answer is "information and education". The longer and better answer is, however, more complex. In our work for life science companies, their suppliers and healthcare professionals, we have developed a general framework of measures and standardised processes that ultimately drive appropriate and compliant behavior. These key process steps involve: defining physician-company relationships; understanding relationship drivers, expectations and areas of conflict; tracing rules and regulations that apply; implementing own or adopting existing policies; educating and testing; and scrutinising and logging. (The measures and processes are known as DUTIES, from the first letter of what is involved in each key step.)

Key steps include defining doctor-company relationships and understanding possible areas of conflict

For life science companies, interactions with physicians are critical to business success. Many stakeholders within the organisation are involved in these relationships. As such, senior management must view any improvements as a critical priority and take a lead in seeing that they are implemented. Changes in one area of the organisation invariably affect other areas. Additionally, a physician's experiences with one part of the organisation affect his/her interaction with other parts of the organisation, especially if these experiences are unfavourable. Only senior management can oversee the full scope and drive important changes.

Addressing key questions

Whether developing policies, training staff, or in daily practice, life science organisations and their staff should be able to address the key questions concerning physician-industry relationships. These questions include the following:

- Do we have a good internal understanding of the various roles that an individual physician may have: clinician, educator, researcher, advisor and administrator (own institution, membership organisation)?
- Do we appreciate the physician's own expectations concerning industry interaction (see Figure 1)?
- Do we understand the guidelines that apply to physicians in their different roles (see references for a listing of many relevant guidelines)?
- What is our organisation's risk profile and tolerance level? Are we willing to take certain risks that may be commercially advantageous but may not spiritually adhere to relevant guidelines and common practice?
- Concerning our company's interaction with physicians, do we know what the boundaries between reality and public perception are? In other words, do we clearly understand what is legally acceptable vs what will be acceptable in the public's eye? And how will we manage the grey area between the two?
- Do we sufficiently communicate, train and test our associates on their knowledge and application of rules and regulations?
- Is there sufficient and appropriate organisational recording and tracking of physician-company relationships and interactions?
- Do we have a formal structure and process in place to clarify grey areas and report and manage infractions? What is our escalation process and when do we involve external agencies?
- Do we inform the physicians we work with on our policies and reiterate their own responsibilities? How do we do this?
- When (and how) do we compensate physicians for their time? How do we determine fair, market-based compensation?
- What overriding geographies and jurisdiction do we consider when managing international physician interactions?

Organisations must understand guidelines that apply to physicians…

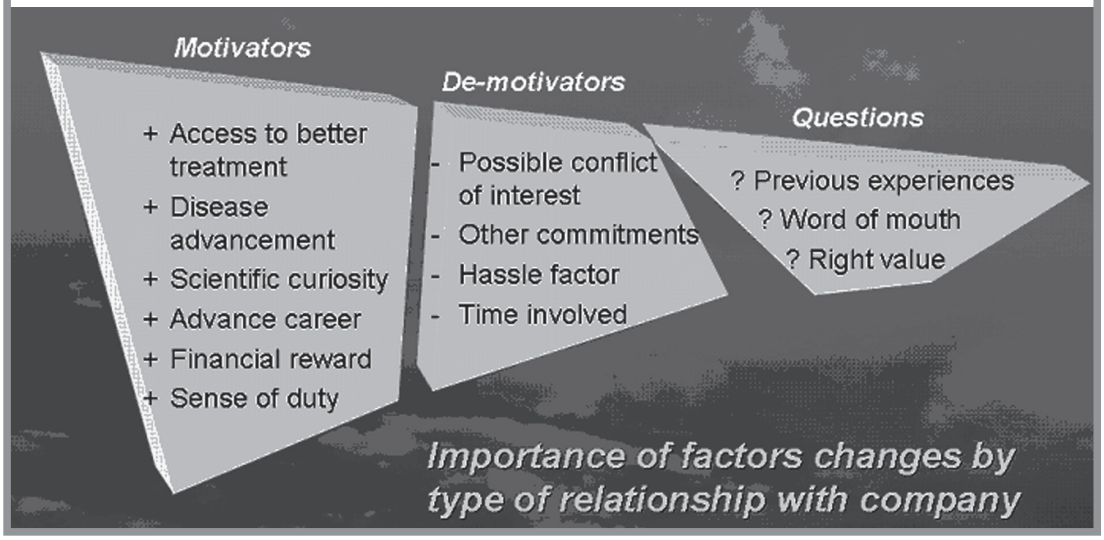
…and determine how to inform physicians they work with on their policies

Managing expectations

Managing physician-industry relationships is not an easy task. Many, often conflicting, rules and regulations apply making this task increasingly challenging. Compounding this is the highly dynamic environment of regulatory changes, and strong public scrutiny.

Healthcare providers, life science organisations, and their associates all are highly aligned in terms of their ultimate interest: delivering the best patient care. However, experience, motivators, and organisational settings will lead us to different starting points and affect our decision-making. It is only through an appreciation of each party's expectations, diligent communication and education, and shared desire for transparency, that we can move past the current challenges to redefine physician-industry relationships.

Figure 1. Possible physician expectations concerning industry relationships



There are a number of possible motivators for physicians to work with industry

It is important to remember that life sciences companies operate in a sector with high public interest

One thing we should never underestimate is that life science companies operate in a sector with high public interest, and that public perception is reality. If employees do not want to see their organisation or indeed their own name connected to this topic in a major news outlet, they had better operate carefully and well within all guidelines that govern physician-industry relationships. And if the guidelines do not cover the situation at hand, take the advice of a former colleague: "If it doesn't pass the smell test, then don't."

References

1. *Atlanta Journal Constitution*, 3 October 2008, www.ajc.com/metro/content/metro/dekalb/stories/2008/10/03/emory_psychiatrist_income.html; *New York Times*, 21 November 2008, www.nytimes.com/2008/11/22/health/22radio.html?_r=1&scp=7&sq=physician%20industry%20ties&st=cse; *Wall Street Journal*, 16 January 2008, http://online.wsj.com/article/SB123206035479087601.html
2. Google News Archive search on Physician Industry Relationships performed on 9 January 2009
3. OIG Semi-Annual Report to Congress, 1 October 2007-31 March 2008, pp 26-27, and 1 April 2008-30 September 2008, p 37
4. OIG's Morris: An enforcer's perspective, AAOS News, May 2008, www.aaos.org/news/aaosnow/may08/cover3.asp
5. OIG website, www.oig.hhs.gov
6. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
7. Institute on Medicine as a Profession, accessed 9 January 2009, www.imapny.org
8. Synopsis of Physician Payment Sunshine Act (S 2029 and HR 5605), www.prescriptionproject.org/tools/solutions_factsheets/files/0008.pdf
9. PhRMA, Code on Interactions with Healthcare Professionals, www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf
10. AdvaMed Revised and Restated Code of Ethics, www.advamed.org/MemberPortal/About/code/
11. AMA website, Current Guidelines, www.ama-assn.org/ama/pub/category/5689.html; Timeline on new guidelines, www.ama-assn.org/ama1/pub/upload/mm/369/ceja_5i08.pdf
12. AMA CEJA report 2-A-07, www.ama-assn.org/ama1/pub/upload/mm/369/ceja_2a07.pdf
13. Website of the Office of Health and Human Services of Massachusetts, www.mass.gov/?pageID=eohhs2homepage&L=1&L0=Home&sid=Eeohhs2
14. Cleveland Clinic website, accessed 3 December 2008, http://my.clevelandclinic.org/media_relations/library/2008/cleveland_clinic_makes_physician_disclosures_available_online.aspx
15. National Institutes of Health, www1.od.nih.gov/oma/manualchapters/ethics/2400-04/
16. European Commission – Enterprise and Industry, http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/communication/communication_en.pdf
17. ABPI's Prescription Medicines Code of Practice Authority, January 2009, www.pmcpa.org.uk
18. English version of Kodex, www.fs-arzneimittelindustrie.de/kodex-fachkreise.html
19. EFPIA, European National Codes of Practice for Promotion of Medicines, www.efpia.eu/Content/Default.asp?PageID=296
20. *New England Journal of Medicine*, 2007, **356**, 1742-50

