Pharmaceutical Executive
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5 Compliance Questions to Ask Yourself...

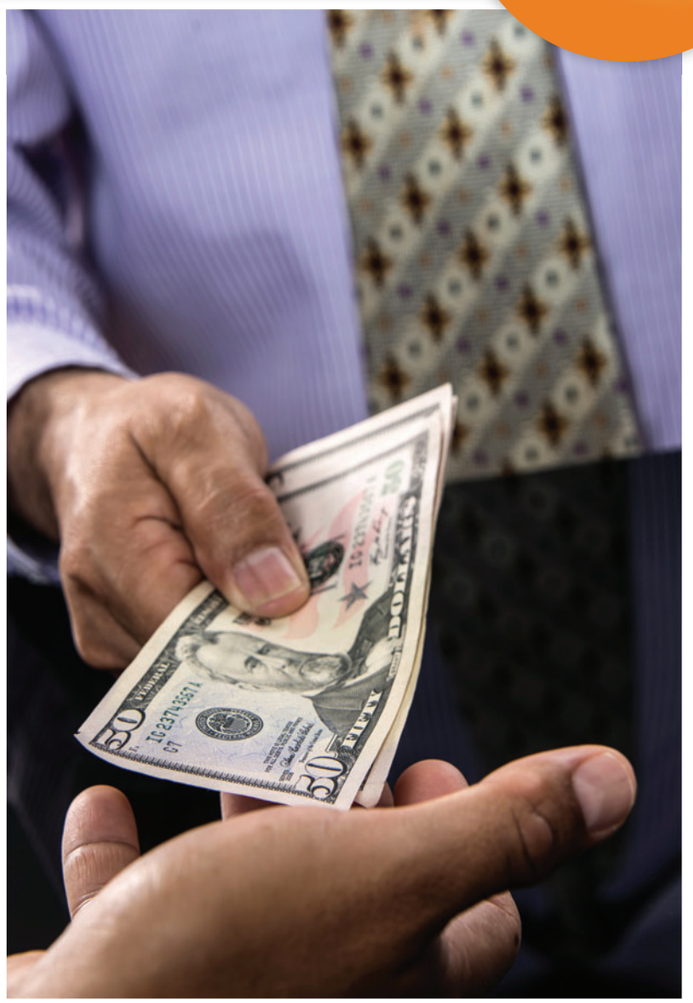
Courtesy of the US Department of Justice

NICE Abroad

Global activities of the UK's National Institute for Health & Care Excellence

Patient Adherence

as a US policy issue



Pharma and the UK Bribery Act

How is the Act shaping up two years after its introduction?

Compliance in the C-Suite

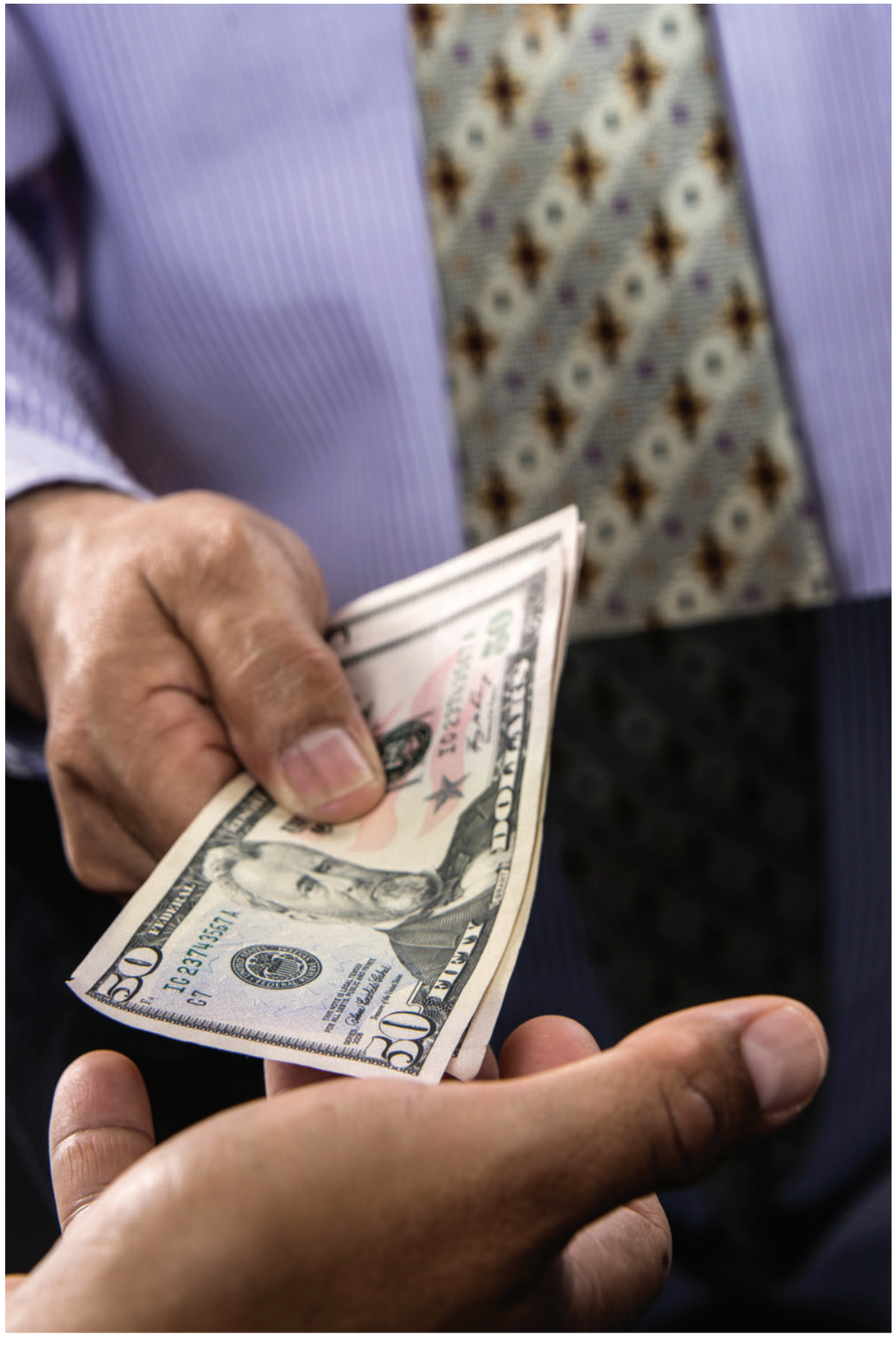
The increasing importance of the Compliance Officer

Croatia

The language barriers that could hamper a smooth EU accession

The New World of KAM

Will Social Media Replace Pharma Meetings?



The UK Bribery Act — Two Years On

Does a recent "sting" exposing pharma companies that defraud the NHS suggest that the UK's Bribery Act isn't working? David Glass and Iain Richardson report.

The UK Bribery Act 2010 (the Act) came into force on 1 July 2011 and created four offences (replacing the patchwork of previous legislation): active bribery; passive bribery; bribing a foreign public official; and a corporate offence of failing to prevent bribery.

How effective has the legislation been in achieving its objectives so far? Well to start, the Serious Fraud Office (SFO), custodian of the Act, does not currently have any pharma companies under investigation, which is a relief. Although that may all change.

The pharma industry recently had more adverse publicity, however, for allegedly corrupt marketing practices, as highlighted by undercover reporters for the Daily Telegraph investigating the market in so-called "specials" drugs. It does not make happy reading. There are suggestions that questionable arrangements within the drugs supply chain (involving "rebates" or "discounts" in many cases) have been used to rip off the NHS on a large scale. These allegations have been denied by the parties concerned.

The Act introduced offences for offering financial or other advantages to another in order to induce them to perform a relevant function

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or activity or reward them for improper performance. Certainly there were financial advantages for both parties but it would appear to be inducing improper conduct rather than improper performance. If bogus discounts were being offered in order to sell specific drugs or induce a pharmacist to prescribe a certain drug, such arrangements are more likely to be considered bribery as it would be a relevant business activity. We cannot help but think that there are much stricter laws and sanctions for such collusion between parties which the Act simply did not envisage dealing with.

Corrupt practices can include so-called "facilitation payments" (eg, paying a foreign public official to approve a marketing authorization) and this practice is outlawed by the UK Bribery Act which is drafted so as to have a global reach.

When it is a question of private businesses wanting to get a foothold into a foreign market where bribery is rife, the public reaction is very often that UK anti-bribery standards are so high that UK businesses cannot compete on a level playing field. The view has, therefore, been advanced by many that the UK bribery legislation is too gold-plated and, indeed, we are expecting the government to review the scope and effectiveness of the with a view, in certain cases, to removing the competitive disadvantage facing UK businesses abroad.

Standards are improving, but it is a long and winding road —the Act may need a few more years under its belt before conclusions can be drawn.

The question of "corporate hospitality" and whether it is simply about goodwill or whether it is about something more sinister is an unresolved issue but it is somewhat apparent, even from observation of the usual watering holes in the City, that there does seem to be much less lavish entertaining going on. This must be a good thing for ethical standards but a commercial world devoid of the human interface would be very drab indeed!

If anything, the Act's introduction of an offence for failing to prevent bribery has probably gone the furthest to help clean up corrupt practices of UK businesses. Companies have had to look within to avoid committing an offence, by ensuring adequate policy and procedures exists throughout their organization which are there to educate and help prevent employees from acting improperly. No longer is accountability resting on a select few, but on the shoulders of every member.

Our conclusion, therefore, is that standards are improving but that it is a long and winding road and that the Act may need a few more years under its belt before conclusions can be drawn.

About the Authors

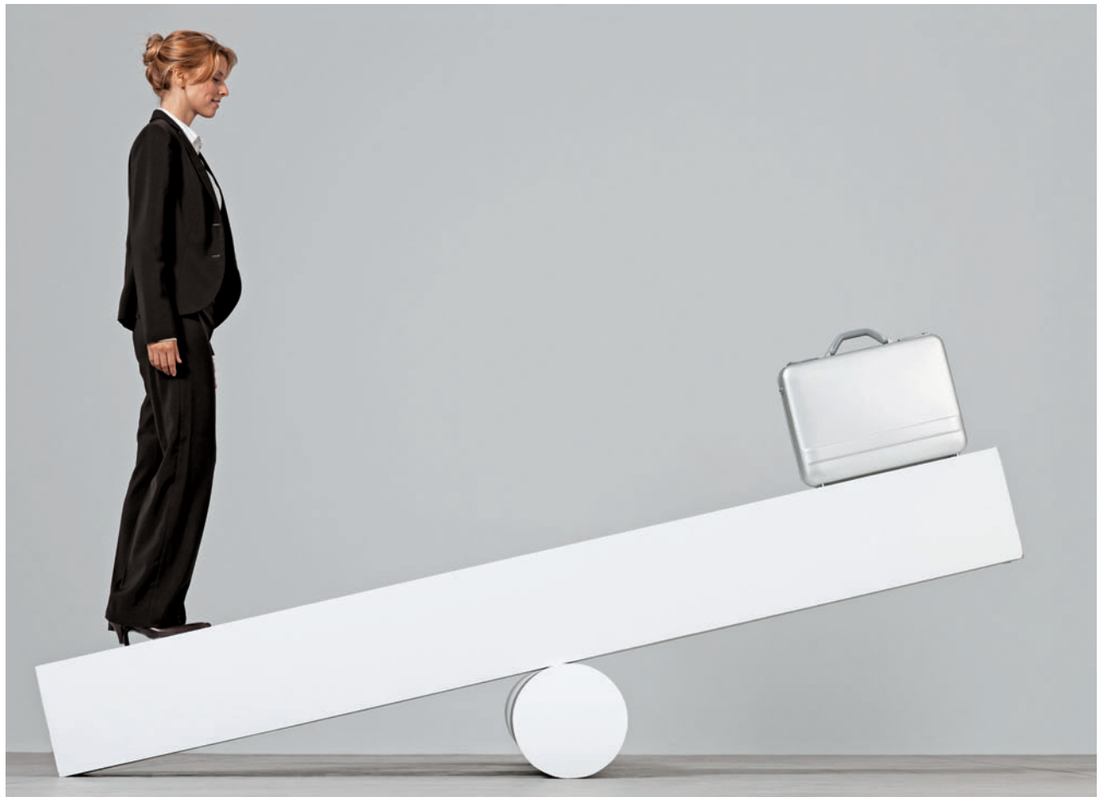
David Glass is Senior Partner and Iain Richardson is an Associate at Pritchard Englefield Solicitors.

Transparency and Data Protection: A Delicate Balance

Pulina Whitaker outlines the European data protection implications of pharma transparency reporting obligations.

"Pharmaceutical companies are now having to navigate complex, and sometimes opposing, regulatory regimes..."

Global pharmaceutical, biotech and medical devices companies are now having to navigate complex, and sometimes opposing, regulatory regimes regarding healthcare practitioner spend reporting.



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Following from the US, European transparency rules are becoming more onerous for the industry. In particular, is the increasing popular requirement to disclose names of healthcare practitioners who receive payments or benefits, whether directly or indirectly. Where healthcare practitioner names are provided in spend reports, and those practitioners receive payments from European organizations, European data protection and data privacy laws will need to be considered.

In Europe, industry bodies, including the European Federation of Pharmaceutical

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Industries and Associations (EFPIA) and the Ethical Standards in Health & Life Sciences Group, have issued proposals to name individual healthcare practitioners when reporting on spending to healthcare practitioners or their organizations to create greater transparency and trust. To put the objective of transparency in context, drug companies currently pay an estimated £40 million ($61 million) each year to British doctors for travel expenses. The prevailing view is that all payments should be broken down per individual healthcare practitioner.

One of the key challenges for the healthcare industry is how to balance their transparency reporting obligations with European data protection legislation to process personal data with consent or only as required in certain circumstances.

European data protection and data privacy restrictions

In essence, European data protection and data privacy requirements mean that healthcare practitioners must consent to the processing of their personal information unless the organization can rely on a relevant exemption.

Relevant exemptions from the consent requirement are where processing the information is necessary to perform a contractual or other legal obligation on the business or otherwise for the business's legitimate interests such as defending or bringing litigation.

The concept of consent is interpreted differently in different European countries. Some countries, such as the UK, interpret consent in a common sense, business-friendly manner. Consent can, to a large degree, be inferred from the conduct or relationship of the parties. In other countries, such as France or Germany, consent is construed more narrowly. Businesses usually need to obtain written consent to most processing activities and consent can be challenged if it is not freely given (eg, at the start of an employment relationship or if conditional upon an offer of employment). International businesses tend to follow the highest standard when dealing with European customers or employees.

A key challenge for the healthcare industry is how to balance its transparency reporting obligations with European data protection legislation...

Relevant exemptions from the consent requirement are where processing the information is necessary to perform a contractual or other legal obligation on the business or otherwise for the business's legitimate interests such as defending or bringing litigation.

There are also restrictions on transferring personal data outside Europe, without consent. Unless the country in which the recipient receives the information as "adequate" data protection laws, such international transfers are prohibited unless, again, a relevant exemption applies or, if the receiving country is the US, the organization has registered with the Department of Commerce's safe harbor regime or the receiving organization has agreed to a data transfer agreement with the exporting organization. These are unlikely to be relevant in the context of healthcare spend reporting so organizations will need to consider whether they have consent from the healthcare practitioners or a relevant exemption applies (such as complying with a legal obligation, in countries where there is a prevailing obligation to disclose names of healthcare practitioners in spend reports).

The penalty consequences of breaching data protection and data privacy rights can, cumulatively, be high. Currently, European countries each set their own levels of fines for data

protection breaches. Under the proposed new European Data Protection Regulation (due to come into force in around 2016), European data protection authorities can levy fines ranging from 0.5% of global turnover or two hundred and fifty thousand euros, for low-level breaches, increasing to 2% of global turnover or one million euros for serious or repeated breaches.

There will be a compulsory reporting obligation with 24 hours of becoming a aware of a data security breach. This report must be made to the relevant data protection authority and the individuals, if the breach adversely affects their privacy.

Global spend reporting strategies

Many healthcare organizations prefer to have global spend reporting strategies, rather than individual country-specific strategies. This is, however, challenging where countries have very different spend reporting requirements (eg, some have legal obligations to do so and others have non-binding codes of practice) and different data protection and data privacy obligations.

Healthcare organizations will do well to inform healthcare practitioners that they will be disclosing details of the healthcare practitioners' names and details of the benefits or payments made or provided to them, including whether or not the information will be transferred to recipients who may be based outside Europe, as a condition of making the payments or benefits. Such informed consent should, ideally, be documented in writing and specifically give the healthcare practitioner the right to turn-down the offer of the payment or benefit if they prefer not to give their consent to this disclosure.

About the Author

Pulina Whitaker is Partner at international law firm King & Spalding.

Five Compliance Questions to Ask Yourself

"Being compliant means understanding people, and their motivations."

At CBI's Compliance Congress this year, Maame Ewusi-Mensah Frimpong of the US DOJ recommended attendees ask themselves five questions to help identify potential problems before they result in an investigation — or worse.

At CBI's 10th Annual Pharmaceutical Compliance Congress earlier this year, Maame Ewusi-Mensah Frimpong, deputy assistant attorney general, consumer protection branch, civil division, at the US Department of Justice, said being compliant means understanding people, and their motivations. Frimpong said non-compliance boils down to a failure of individuals, and offered five questions for chief compliance officers to ask themselves about their colleagues.

In addition to taking a close look at pharma's internal processes, manufacturing facilities and corporate policies this year, the US Justice Department (DOJ) — in the name of "protecting consumers where they are

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most vulnerable," according to Frimpong – is also placing a "focus on people," since processes and policies (at least publicly-circulated processes and policies) don't typically break the law; people do. "We know there are enormous cost pressures, but you can't sacrifice safety under these pressures," said Frimpong.

To that end, Frimpong recommended that attendees ask themselves five questions about the group of people they work with, to help identify potential problems before they result in an investigation or worse. In summary, Frimpong's questions are:

1. Do we have the right people?

Are they experts in their specific task areas? "People are not fungible," said Frimpong. Given the complexity involved in certain manufacturing practices, for example, it's crucial that the right person is working in the right role.

2. Do our people have the right incentives enabling them to see problems, report problems, and fix problems?

Frimpong said strong internal communications are key to facilitating diligent compliance programs.

3. Are our people satisfied and engaged with the company and their jobs?

Frimpong said the departure of key people can sometimes lead to lapses in compliance, citing SB Pharmaco, a GSK subsidiary, and the manufacturing deficiencies at the company's (now-closed) plant in Cidra, Puerto Rico.

4. Are people and policies working in harmony?

Companies should set realistic goals, and refrain from crafting compliance programs and procedures that can't be met. Unrealistic standards are doomed to fail, said Frimpong.

5. Do we, as chief compliance officers, know what our people are actually doing?

Given the size and scope of many large, multinational pharmas, it's important that leadership make a concerted effort to communicate with and assess the performance of specific individuals whenever possible.

Frimpong underscored the problem – and gave examples – of companies who've put patients in harm's way in service of the bottom line, saying, "when companies put profits over patients, everyone loses."

Compliance in the C-Suite

"Compliance issues, and by extension chief compliance officers, are gaining momentum."

Compliance officers have risen into management's highest ranks, by choice in some organizations, and by government decree in others. Either way, their importance as a strategic partner can hardly be understated, writes Ben Comer.

These days, headline-grabbing, reputation-damaging investigations by government into pharma business practices, at home and abroad, seem almost as frequent as new drug approvals. In addition to worrisome compliance areas like off-label promotion in the US and bribery in global markets, the Physician Payment Sunshine Act is expected to come online next year, which could put executives in the time-consuming position of having to defend legitimate business interactions with healthcare providers.

Government has also signaled a growing interest in R&D and medical affairs, particularly in relation to clinical investigator controls, reporting from clinical programs, and how contract

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OIG'S CORE ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

1. Implementing written policies and procedures.

2. Designating a compliance officer and compliance committee.

3. Conducting effective training and education.

4. Developing effective lines of communication.

5. Conducting internal monitoring and auditing.

6. Enforcing standards through well-publicized disciplinary guidelines.

7. Responding promptly to detected problems and undertaking corrective action.

(OIG's full guidance can be found in the Federal Register, vol. 68, no. 86, May 5, 2003.)

research organizations are and should be monitored.

All of this is to say that compliance issues, and by extension chief compliance officers, are gaining momentum and have moved from the background of business operations to the foreground, and for good reason

Government is taking an active interest in not only whether or not rules are being broken, but also whether companies have duly empowered compliance teams by creating programs, policies, and management structures designed to prevent compliance issues from arising in the first place. Organizations putting the correct structures and processes in place, before federal investigators come knocking, can save a lot of money and time by avoiding costly settlements and Corporate Integrity Agreement (CIA) negotiations, in addition to placing themselves in the exclusive company of other organizations unbound by looming litigation and the kinds of red tape that kills deals and collaborations.

Core elements of compliance

But there are ways to get right with government before it comes around to scythe company profits, or individual careers. In 2003, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released guidance on compliance programs, including seven core elements for program effectiveness (see sidebar). Every chief compliance officer ought to be able to name these off without hesitation.

Number two on the list of OIG guidelines states that a compliance officer should be given the "authority to report directly to the board of directors and/or the president or CEO" of the company. A report on compliance best practices for the pharma industry released by Cutting Edge Information last summer states that in the area of compliance, "appearances

matter a great deal, and regulatory agencies want to see that companies are doing everything they can to ensure adherence to the rulebook."

Board on board

The responsibility of the board, when it comes to compliance issues, extends beyond staying awake during a program briefing. At the OIG-hosted Pharmaceutical Roundtable on Compliance last February, participants said that in addition to being trained and educated on compliance issues, board members should consult with third-party, independent compliance experts; provide review and oversight of audits and identified risk areas; interact routinely with internal compliance officers; and "convey messages about the value and importance of compliance (including as a competitive business advantage)," according to a report on the roundtable's findings.

While the board of directors shouldn't muscle its way into developing specific processes and solutions for mitigating risk — the remit of the compliance team — they should be getting regular progress reports from their compliance officers.

Communication to asset risk

In addition to setting the tone on transparency and the importance of compliant business practices, top leadership also needs to be kept abreast of ever-emerging risk areas the company faces. This requires well-established lines of communication between the executive committee and the chief compliance officer. As the point person between business units and management, compliance officers must cast a wide net to capture information.

To properly assess and prioritize risk, compliance officers and their teams need lots of friends across the company. Human resources, for example, is an important trove of information, and a necessary strategic partner for compliance personnel.

> The compliance officer position continues to evolve, but already can be viewed as a strategic partner...

Compliance as business strategy

Finding the right training and educational best practices for employees is important, and so is the establishment of a robust documentation process, which can be used to show regulators that a company has acted in good faith, and has promoted the right kinds of policies and practices, even when a single employee makes a mistake, or goes rogue. Following OIG guidance, in addition to PhRMA's code on interaction with healthcare professionals, and building a solid internal documentation process can also help protect executives from the Responsible Corporate Officer Doctrine, or Park Doctrine, which has recently come back into vogue with some regulators (including FDA and DOJ).

In compliance, defensive measures are part and parcel of a strong offense, inverting the old adage: the best offense can in fact be a strong defense against non-compliance. Employees must be certain that their superiors won't protect unlawful business practices, internally or externally. But compliance also needs to be able to defend company practices, if there is ever a question from regulators.

The compliance officer, still a relatively new position, continues to evolve, but already can be viewed as a strategic partner. A good compliance function and a company with a good record is good for business. Compliance is no longer just a box to check. Its strategic function within the organization is more important than ever.

Ben Comer is Content Manager at Pharm Exec.

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NICE Around the World

Leela Barham charts the progress of the National Institute for Health and Care Excellence's international arm.

The National Institute for Health and Care Excellence (NICE) is widely known not just within England where its recommendations are made and applied, but also much further afield. Its not-for-profit arm, NICE International, was set up in 2008 to "contribute to better health around the world through the more effective and equitable use of resources."

Dr Kalipso Chalkidou is NICE International's founding Director. She has a small team to support her, just seven Whole Time Equivalents in 2013/14.1 That team is also able to work with other partners and gets advice from the NICE International Advisory Group. The advisory group includes members from across academia, governments, and from Non-Governmental Organizations (NGOs).

NICE International's services range from adapting guidelines and providing training, to setting up national purchasing and reimbursement processes.

"There isn't a continent that NICE International hasn't been involved with"

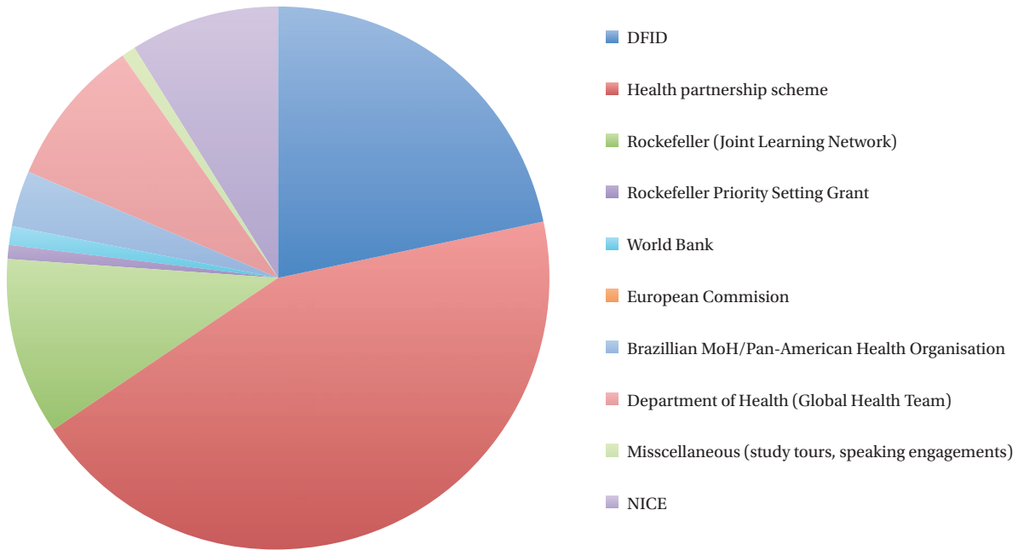
Wide reach

NICE International had delivered projects in 14 countries by 2011 and engaged with or partnered with some 32 more. By 2012, that had increased to delivering projects in 35 countries and engagement or partnership with 40 countries in total. There isn't a continent that NICE International hasn't been involved with. Some of their more relevant work for pharma in 2012 includes:

- Thailand — quality in healthcare events and multi-country discussion on priority setting institutions in health with the Centre for Global Development and Thailan's Health Interventions and Technologies Assessment Program.
- Taiwan — supporting the set up of a new centre for health technology assessment.
- Japan — discussing the role of economic evaluation with the Ritsumeikan University in Japan.
- Brazil — ANVISA visited NICE to learn more about pricing and reimbursement of medicines.

NICE International isn't just funded by the countries it works with; it has also been successful at gaining funding from global agencies such as the World Health Organization (WHO) and the World Bank and the UK's Department for International Development (Figure 1).

Figure 1



Source: Data from NICE Board Papers January 2013 Item 04 Appendix A

HTA around the world

Health Technology Assessment (HTA) has been on the rise for some time. NICE International is part of that growing popularity of HTA. But the implications are not just in relation to more countries using HTA but also, if you're an optimist, better HTA. If you're more cynical, then it could be more misuse of HTA especially since countries will inevitably be 'bolting on' HTA and/or making refinements to what is already there. After all, NICE International can't control how their work is used locally. There will be a temptation of countries to pick and choose from NICE Internationals suggestions.

Not so NICE?

NICE International has not been free of criticism; Stephen Whitehead, Chief Executive at the Association of the British Pharmaceutical Industry (ABPI) has criticized NICE international's work particularly in Romania. He characterized that work as fundamentally undermining the value of medicines, many exported from the UK. But just what was that Romanian work? (See Sidebar: Nice International in Romania)

Truly global

NICE International must believe in a growing level of demand for its services, committing to a pay bill of over a half a million in 2013/14 compared to a little over £400,000 ($608,000) in 2012/13. That growth in demand is despite a very small budget for business development (a measly £40,000 per year), so it is building business pretty successfully. It's also sure that it'll have over £1 million ($1.5m) of income for this financial year, with a mix of work from existing clients and new ones. One of those projects is ADVANCE-HTA, where NICE with partners, has secured three years of funding from the European Union to 'advance and strengthen the practice and use of HTA'. And its ambitions go far beyond Europe. With NICE International also seeking funding to develop a worldwide HTA network,[2] its reach is becoming truly global.

References

1. NICE Board Papers January 2013 Item 04 Appendix A
2. Ibid.

About the Author

Leela Barham is an independent health economist.

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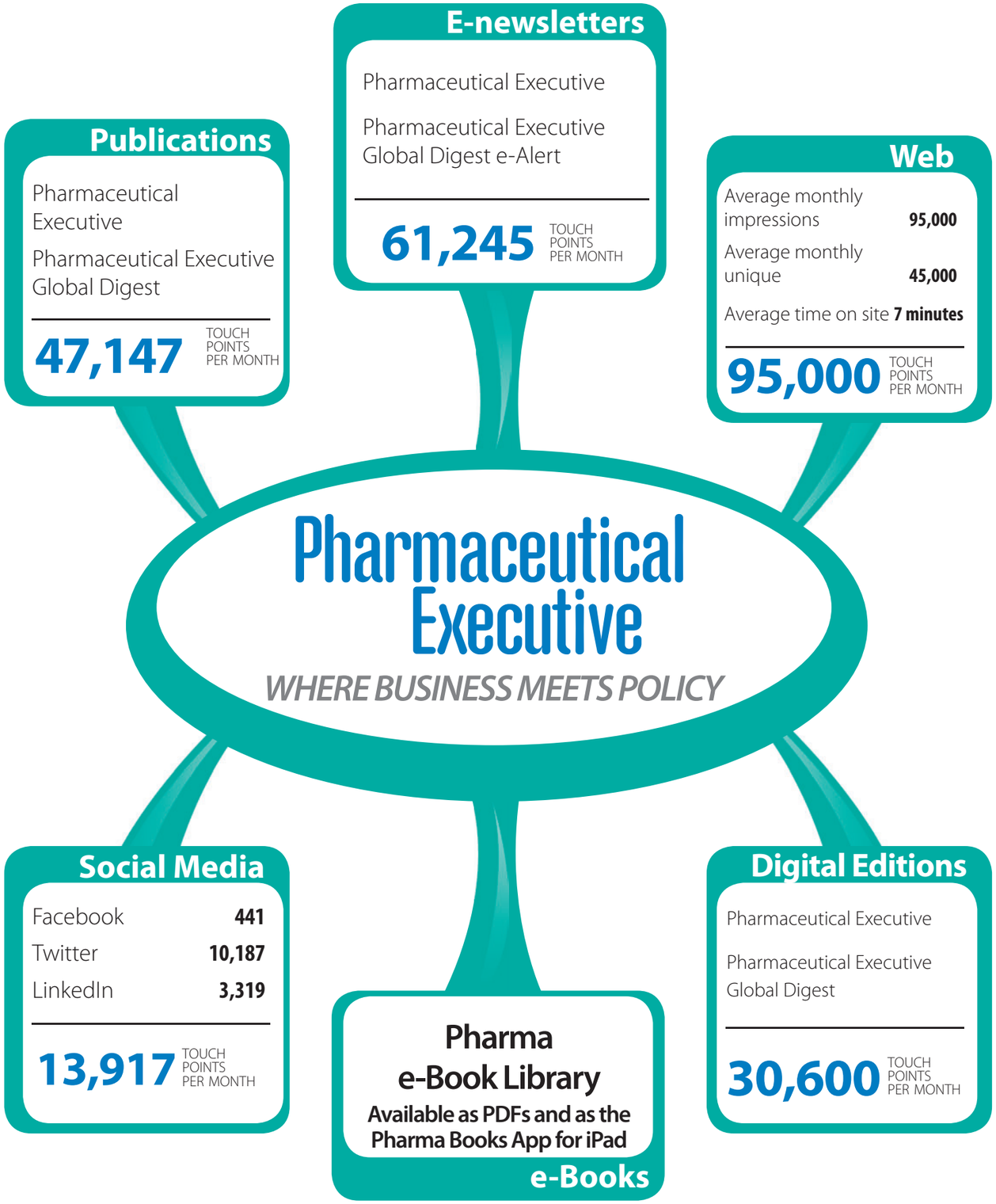

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NICE INTERNATIONAL IN ROMANIA

NICE International's arguably most controversial project to date was their work on 'reviewing the content and listing processes for the Romanian Basic Package of Health Services and Technologies'. In a 69-page report published in January 2012, NICE sets out what it did, and what it recommends is done.

Controversial recommendations

49 recommendations were split between those to be done in the immediate term (within 12 months), medium term (two to three years) and long term (four to five years). The recommendations go far beyond just how to do 'good HTA'. Some of them are explicitly about cutting coverage and toughening up on pricing. For example, NICE recommended that Romania

- 'implement recommended drug delisting's and restrictions'
- 'consider claw back tax on medical devices' (although not focused on medicines, pharma may wonder whether NICE International could be suggesting claw backs in other countries, and Romania already has a claw back on medicines)
- 'extend internal reference pricing to further therapeutic reference pricing model'
- 'initiate negotiation to reduce prices of key molecules'
- 'consider introduction of risk sharing arrangements for high cost technologies'
- 'expand application of HTA findings to price setting for health technologies'
- 'explore use of centralized competitive bidding processes for major drug classes'

NICE also applied what it characterized as 'fairly simplistic' cross national assessment of cost effectiveness for the top 50 drugs used in Romania. It basically worked out what Romania should pay if they paid in line with their GDP by multiplying the UK price by the ratio of Romanian/UK GDP. These were then translated into 'target percentage cuts' so that these drugs would be of similar cost effectiveness in Romania as set out in other countries HTA reports (and most of these are reports are from NICE but from Australia and other parts of the world too). And some of those cuts are likely to be pretty unpalatable to pharma companies:

- highest cut of 85 per cent for simvastatin
- lowest cut of 42 per cent for quetiapine.

Such an approach is both worryingly formulaic and goes against the grain of making decisions fit for the local context and provides a tempting hit list for a cash constrained country, and further raises the specter of parallel exportation and downward price spirals across Europe.

And the warm words that NICE International believe that 'addressing the broader structural factors influencing the efficiency of Romanian healthcare delivery has the potential to deliver a significantly greater contribution to the longer term sustainability and affordability of the overall system than the short term correction likely to be achieve through the construction of a negative list' are likely to be of cold comfort to pharma.

Romania now

Romania has made some changes to their approach to pricing and reimbursement. Some are in line with NICE International recommendations. For example:

- A formal HTA unit has been set up within the Ministry of Health (although it wasn't yet working fully as at December 2012).
- Reimbursement dossiers now need to include relevant clinical studies results; relevant cost-effectiveness studies from France and the UK; prices approaches in other EU countries; cost comparison with drugs used for the same indication.
- Central procurement of medicines for emergency care units
- Blocking parallel exports of oncology medicines
- The reimbursement list is also due to be updated this summer.

But according to a local source in Romania, not much has really happened as a result of the report. That may be a source of relief for some, and disappointment for others.

Patient Adherence and Public Policy in the US

At Frost & Sullivan's recent Patient Adherence Congress, Joe Ganley, Director of State Government Affairs at McKesson, discussed public health policy and its implications for patient adherence. Here, he provides PEGD with some highlights of that presentation.

PEGD: Why is adherence getting so much attention lately?

Medication adherence has always been important to maintaining patient health; however, the enormous economic pressures that have historically plagued the healthcare system have placed greater emphasis on reducing costs. Increased adherence leads to overall reduction in healthcare costs in America. For example, according to a recent report from the Congressional Budget Office (CBO), "a 1% increase in the number of prescriptions filled by Medicare beneficiaries would cause Medicare spending on medical services to fall by roughly 0.2% ($1.7B)." Put another way, non-adherence costs the healthcare system nearly $290 billion annually and accounts for approximately 13 percent of the total healthcare expenditures.

> "Non-adherence costs the healthcare system $290 billion annually..."

PEGD: Why is adherence a policy issue?

The high cost of healthcare has reached a critical condition, thanks in part to two simple facts. The largest customers of the healthcare system are the federal and state governments, and those entities are facing staggering budget deficits. From a government perspective, the need to reign in healthcare costs, was long a political priority for some, is now a fiscal necessity for all of us.

From a public policy standpoint, there are three trends originating from two landmark pieces of legislation — the Affordable Care Act and HITECH Act:

- Delivery and Payment Reform: Accountability and shared savings
- Insurance Reform: Expanded coverage, but at a price
- Health IT: Meaningful use to foster connectivity.

PEGD: Which public policies are impacting adherence either positively or negatively?

There are some macro trends in public policy that will impact adherence significantly. The industry is shifting

from a closed "black box" system where there was little transparency about costs of patient care to a more open

"Non-adherence costs the healthcare system nearly $290 billion annually..."

system where patients will have greater visibility and accountability for the cost of care, and where providers are paid not based on the number of tests/procedures/visits but rather on healthcare outcomes. The Affordable Care Act in particular has made both patients and providers more accountable for the costs of healthcare, which should incentivize better medication adherence since it is proven that good adherence leads to positive health outcomes at lower costs.

PEGD: What new challenges does this present?

First, if we want patients to take more control over their own healthcare, we need to dramatically improve connectivity. To make an informed decision about your healthcare requires a broader view of the system for patients both in terms of cost and quality. Additionally patients need better connectivity to their doctors, and the ability to use Patient Health Records (PHR's) to see and communicate with their provider about the complete picture of their medical history.

Secondly, we may need to rethink some of the regulations that have traditionally governed healthcare. For example, regulations prohibit pharmaceutical manufacturers from offering co-pay assistance to "federal beneficiaries" both through Medicaid and Medicare. But what about new enrollees who purchase commercial insurance through an exchange and has the cost subsidized under provisions of the ACA? Is that person a "federal beneficiary" and are they therefore excluded from a manufacturer sponsored co-pay assistance program? Furthermore, if they are to be excluded how can service providers like McKesson who provide these co-pay assistance programs distinguish the "subsidized" from the "unsubsidized" at the pharmacy counter or in the providers office? If these questions cannot be answered, it may be more challenging for tens of thousands, if not more, of new enrollees to benefit from co-pay assistance programs. While our co-assistance programs have some unique methods to help screen out government beneficiaries, McKesson will continue to inform and seek clarity around any upcoming policy decisions.

PEGD: How do you see Healthcare IT's role in the changing industry?

Simply put, healthcare IT is foundational to everything we're trying to do in healthcare. Whether it's improving quality, giving patients more accountability and control, reducing costs and inefficiencies, preventing medical errors, or improving quality — a better connected interoperable healthcare system is essential. Healthcare IT is not the silver bullet. But it is an essential part of the solution to these challenges. It's necessary, but not alone sufficient.

PEGD: What role can industry play in impacting policy to promote adherence?

Adherence will be paramount in reducing cost, measuring HCP performance, and overall system reform. The industry must become much more tough minded about quality transparency and measurement, including unbiased ROI studies to measure the impact of adherence.

The healthcare industry needs to come together and focus on long-term reform of the system rather than short-

term competitive agendas. Manufacturers, providers, and other healthcare services must work together to get it right for our business and our patients.

While the industry is shifting, healthcare is notoriously slow to adopt new methodologies.

Conclusion

When I was a kid, I remember going with my dad to the bank to deposit his paycheck. He took his check and handed it to a person who verified his identification and processed his deposit. Think of how far we've come. Last week, I deposited a check into my account by taking a picture of it with my smart phone and the funds were available immediately. Now, look at healthcare. When I was a kid, your medical record was a clipboard that hung on the end of the bed, and every caregiver who treated you would add their notes to the next page. Recently, my wife and I were meeting with her OB/GYN trying to resolve an allergy issue that could affect the delivery of our baby and there was the doctor, in 2013, going through a paper record of my wife's allergic reactions over the last year or two. It is remarkable how far we have to go.

While the industry is shifting, healthcare is notoriously slow to adopt new methodologies. This gives manufacturers the ability to understand and get involved in public policy. One of the most cost effective and impactful solutions to healthcare reform is better medication adherence. Brands are encouraged to find opportunities to provide guidance and services to help consumers (HCPs, pharmacists, patients) to differentiate your product while improving patient outcomes. With reimbursement directly linked to outcomes, and outcomes improved by adherence, everyone in healthcare will be looking to enhance and better understand adherence.

About Joe Ganley

Director of State Government Affairs, Corporate Public Affairs at McKesson, Joe Ganley has more than 13 years' experience in the fields of public affairs, government relations, corporate communications, crisis management and political campaigns.

McKesson Corporation is a healthcare services and information technology company currently ranked 14th on the FORTUNE 500. Its Patient Relationship Solutions (MPRS) was created to deliver patient adherence programs that enable manufacturers to develop closer relationships with consumers.

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Croatia's EU Accession: Mind Your Language

"Croatia's challenges — and sensitivities — are rooted in the region's history."

Renato Beninatto explains why pharma companies will find language one of the major obstacles to Croatia's smooth accession to the European Union.

How do you say in Croatian, "It's a new day for pharmaceutical marketing and regulatory compliance?"

I don't know the answer myself because I can't speak Croatian, but just because it's not my native language doesn't minimize the need to understand its importance in the scheme of new pharmaceutical regulatory requirements.

On July 1, Croatia became the 28th member of the European Union (EU). Its entry not only boosts the number of official EU languages by one — up from 24 to 25 — it brings a number of new challenges to pharmaceutical companies that market within the EU. Challenges, in fact, that are beyond the status quo.

The European Medicines Agency (EMA) legally obligates pharmaceutical makers to

Peter Barritt/Getty Images

provide translations of their product information into each EU country's official language, and in the case of the Croatian language itself, the situation is particularly tricky.

Four languages

Croatia's challenges — and the sensitivities — are rooted in the region's history. When Yugoslavia existed as a political entity, the nation's official language was known as Serbo-Croatian, a multi-dialect tongue that was standardized in the 19th century. Since 1991, however, when several regions broke into distinct countries that once formed Yugoslavia, the Serbo-Croatian language no longer exists officially. Instead, tongues that were once considered dialects — and from a linguistic perspective alone they basically still are — are now recognized as four distinct languages: Croatian, Serbian, Bosnian, and Montenegrin.

Most outside observers wouldn't notice the slight differences between the four in terms of their core syntax, vocabulary, and pronunciation. All four are mutually intelligible, and in fact, some dialects of Croatian are harder to understand between speakers from different regions of Croatia than, for example, the differences between Croatian and Serbian speakers.

> Croatia's EU accession raises marketing complexities, but also provides the chance for pharma producers to evaluate their global strategy...

The challenge, however, is to ensure pharmaceutical marketers understand how important it is to convey a clear understanding of the area's local norms. Serbo-Croatian may be passable from a compliance standpoint as far as comprehension is concerned, but unless the distinction between Croatian and Serbian are made clearly and without error, companies run the risk of insulting and, possibly, alienating potential buyers.

Probably the biggest difference — and the greatest pitfall — is the way these languages are written. The two major dialects, Serbian and Croatian, are written in two different alphabets. Serbian is written in its own version of the Cyrillic alphabet, similar to Russian, and Croatian is written in the more Western-friendly Roman alphabet.

Both regions' natives are highly aware of the subtle differences between their dialects, and they care passionately about their language out of a sense of national and ethnic pride. Accuracy, clarity and consistency form the cornerstones of high-quality translation in any industry, but they are particularly important in the pharmaceutical segment when a person's health and well-being are literally at stake.

The reason for compliance is clear and urgent. Consumers and healthcare workers rely upon product packaging to guide them in making the right product choice as well as using it properly. Errors in either of these areas could mean injury, even death and years of legal fallout.

Linguistic localization

To navigate ever increasing EU linguistic localization and regulatory challenges, pharmaceutical producers should ensure their strategic partners maintain the following knowledge and expertise:

- In-house, native-speaking teams certified in clinical translation for each market.
- Independent medical consultants who provide in-country reviews for

linguistic and technical accuracy.

- Back translators who are native English speakers, highly proficient in the target language and knowledgeable in life sciences.
- Desktop publishing professionals skilled in meeting the requirements of mock-ups and in the case of the EU, specimens for the Quality Review Documents (QRD).

Croatia's EU accession is significant for the former Yugoslav republic, which is trying to attract direct foreign investments. The World Health Organization's 2011 Croatia Pharmaceutical Country Profile reports that domestic Croatian pharmaceutical manufacturers hold only 20 percent market share by value produced, leaving an opportunity that may well benefit pharmaceutical producers.

Croatia's EU accession raises EU marketing complexity, but also provides the chance for pharmaceutical producers to evaluate their strategic approach to markets globally as well as their Croatian strategy. As growth opportunities in developed markets inevitably begin to slow, pharmaceutical producers will continue to shift their attention toward emerging markets.

A recent Booz & Co. report, Pharma Emerging Markets 2.0 — How Emerging Markets Are Driving the Transformation of the Pharmaceutical Industry, based on interviews of 12 of the top 15 global pharmaceutical companies, found that 52 percent of the top managers participating in the survey indicated that, by 2018, more than 30 percent of their respective companies' revenue will come from emerging markets.

Although tapping emerging markets to generate compelling new revenue streams is far from a new idea, doing it successfully is not a given, even for the most well established companies. Among the key tests for pharmaceutical companies in emerging markets is their ability to localize their market-specific efforts successfully. They must also be sure to meet the regulatory standards in each country as they relate to medicinal product translation.

As the Booz & Co. report highlights, the biggest mistake companies make in emerging markets is "insufficient tailoring of approaches to local needs," according to 27 percent of the pharmaceutical executives surveyed.

Certainly, emerging markets like Croatia represent huge growth opportunities, but it's imperative that pharmaceutical producers take a strategic and thoughtful approach that carefully considers localization and language strategies to maximize performance in all markets worldwide.

Or, as my Croatian-speaking colleague would say "It's a new day for pharmaceutical marketing and regulatory compliance" in a way consumers in Zagreb can understand — „Ovo je novo vrijeme za marketing lijekova i uskladivanje s propisima."

It might mean the same as its English counterpart, but there is no comparison in what it can do for increased sales and customer loyalty in Croatia.

About the Author

Renato Beninatto is Chief Marketing Officer at Moravia, a globalization company based in the Czech Republic with U.S. headquarters in Newbury Park, CA. Follow Renato on Twitter @renatobeninatto.

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The New World of KAM

Mark Sales asks, are you reporting the opportunity in key account management?

We have all read about the changing commercial model in the biopharmaceutical industry, which comes at us under various guises depending on which consultancy you are spending your hard-earned dollars on.

A lot has been said and written about the reason for this change, but the truth seems to lie somewhere between: The pipeline gap that has driven a need for cuts in expenditure to maintain margins and therefore dividends to those careful investors who saw pharma as a “safe bet” and companies taking this opportunity to become more focused on an synergistic interaction with its stakeholders.

What we see from this is a need to implement key account management properly, and as an industry we are there in varying guises. You may recognize one or two of the following.

Did your organization take the easy (and some may argue foolish) way out and reduce your sales organization, then simply rename your remaining reps as key account managers? They are the same people, same skills, training, outlook, metrics of success plus an iPad ... and the same outcome with people giving the three-product detail to physicians who don’t want to see them.

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The next group hired the expensive consultancy, re-organized around account teams and spent a fortune retraining their best people to treat the account like a business and to deliver local market access strategies — they are even using their iPads for cost-effectiveness modeling. And you're measuring the sales of this to measure your success.

Or maybe you are the third type of company, which has implemented proper key account management and then asked the question "What does success look like?" These companies know that in order to really change behavior they need to change the measure of success. The advent of the iPad in the customer-facing team presents a unique opportunity to do this.

The new world is all about working with multiple stakeholders, but the classical measure of sales is not linking this back to anybody but the physician writing the prescription. We need to remember the reason we implemented KAM: a need to influence and build relationships with multiple stakeholders.

> We need to remember the reason we implemented KAM...

There is broad agreement that in order to change the behavior of KAMs metric is needed that can be implemented across multiple stakeholders, has a clear link to eventual prescribing, has strong benchmarking and also links to key drivers/actions in which to increase it.

We are now in a juncture in insight collection where the iPad/tablet-carrying KAM/rep/MSL will drive a paradigm shift in how much and how cheaply data is collected. We currently invest large sums in paying physicians in small quantities to evaluate our performance at a level that does not allow comparison at a level other than country. Imagine every customer-facing person at the end of every interaction offering up a 60-second survey measuring our new metric (with the robustness and benchmarks mentioned above). The mind boggles at the volume of data we can start to collect — 3,000 people in the US collecting only two surveys a day gives over a million data points a year. Suddenly we are in a new place; the paradigm shift has happened, and we are not replacing but augmenting our call and sales data with a relationship metric that could be a predictor for future behavior, one that we know which levers to press in which to most effectively increase...

Welcome to the new world, brought to us by a $400 iPad and some creative thinking.

Mark Sales is Head of Global Brand & Stakeholder Management, Kantar Health.

Will Social Media Ever Replace Pharma Meetings?

It's been threatened for years, but Peter Houston thinks that speaker-led events will remains a draw because they offer something unique.

I read a blog post recently where Brian S. McGowan, PhD, predicted 50 percent of medical meetings will be replaced by virtual courses within five years. I don't know about the number, but the logic is probably right. I'm sure a lot of CME can be delivered as well online as it can in person, possibly better.

The post got me thinking about the future of industry meetings in general — militant pixelheads have had conferences and congresses on the same death-watch as newspapers and magazines for years. It's intriguing then that the possibly the only industry on the planet that seems to have more conferences,seminars and meetings than the pharma industry is the social media sector. Speaker-led events are a long established way for people to learn and share ideas. Big Pharma and upstart social media agencies may be at the opposite end of the evolutionary scale of business, but they definitely have one thing in common — massive, rapid change — and in times of disruption, learning is everything.

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So when we can access every musing of our industry colleagues through their blogs, Twitter streams and YouTube channels, why do we still find real world events such a strong draw? With all this knowledge literally at our fingertips why do we still get on planes and buses and trains and travel for hours to listen to presentations we'll eventually be able to get at our own desktops.

The stock answer is "the hallway conversations", the people you can actually meet and interact with at conferences. Seth Godin is reported to have said that delegates to Ted conferences should skip the talks, watch them later online and make the most of the time to meet other people.

Fair enough, but is the potential of a meaningful conversation enough for me to pay $1,500 to attend a one day event? Aren't you just going to connect with everyone you meet on LinkedIn anyway. Right?

No, connecting with everyone and anyone is a bad idea. Writing on the Harvard Business Review blog network VP of Social Media at Vision Critical Alexandra Samuel says you should run the "Favor Test" before connecting with anyone on LinkedIn. You need to ask yourself, would I do a favor for this person, or ask a favor of them? If not, don't connect.

> The enduring benefit of face-to-face meetings is we get to qualify connections, vetting them according to common interest...

I meet a lot of people at a lot of conferences that I never connect with on LinkedIn. I'll diligently file all their business cards in my Rolodex, but I'll only make the effort to send a LinkedIn invitation to the people that I actually relate to face-to-face. Conversely, I've also met people in the real world after connecting online and wondered how they ever made it past security.

The point is, the enduring benefit of face-to-face meetings is we get to qualify connections, vetting them according to common interest, how well they actually communicate in real-life and whether we feel we can trust them.

In an article for Forbes last year, Susan Tardanico wrote, "As human beings, our only real method of connection is through authentic communication." She goes on to say that only 7 percent of communication is based on the written or verbal word, 93 percent is based on nonverbal body language. That's a fairly big ratio in favour of face to face meetings.

Social media is great for recommendations when you're looking to buy a book or a new coffee maker, but are you going to buy a manufacturing line or engage a marketing agency purely on the number of 'Likes' they get? Unlikely. You want to look into the eyes of your suppliers and partners and an industry conference is the perfect place to cram lots of those vetting sessions into a relatively short space of time.

Economics, not Facebook, will have a bigger impact on the future size of the professional meetings industry. Revenues are generally flat, but it's squeezed travel budgets forcing the non-attendee agenda, not the magical powers of social networking. According to an infographic produced by Pharm Exec colleagues over at CBI, 32 percent of businesses were expecting to cut budgets for industry events last year.

The same infographic highlights a list of social media tactics that meeting organisers are doing to improve the experience for delegates and boost their numbers. Mobile apps are being used by 33 percent of conferences with 42 percent intending to release an event app in the near future.

LinkedIn and Facebook are being used to communicate with delegates by over 70 percent of organisers; Twitter by over 60 percent; and blogs, podcasts and YouTube by more than 30 percent. Streaming video and WiFi availability are also on the agenda.

Economics, not Facebook, will have a bigger impact on the future size of the professional meetings industry

Clearly the pharma sector's conference organisers are working hard to combat the twin pressures tightening travel budgets and technology to keep their events valuable and relevant. The best case scenario for attendees is that marginal events will quietly fade away leaving the absolute best to survive and thrive, the best being those with the best learning opportunities and the best real-world and online networking opportunities.

About the Author

Peter Houston is former Group Content Director for Advanstar Pharma Science. He is now an independent media consultant and founder of Flipping Pages.

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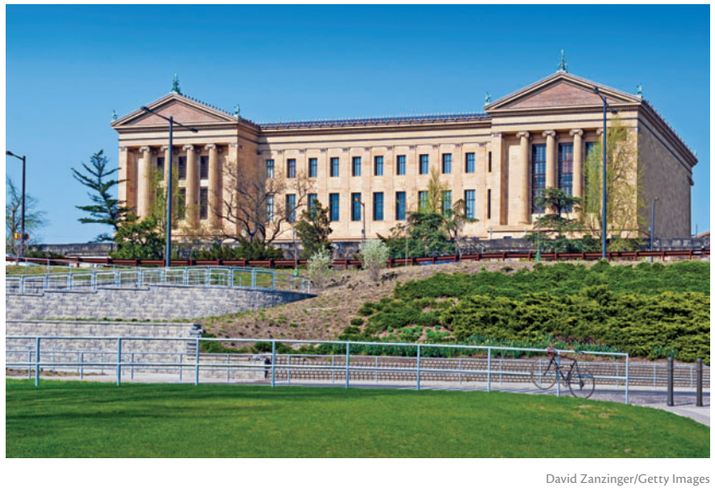

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Pharmaceutical Executive Digest Europe provides industry intelligence so managers in the European pharmaceutical community can advance their business, management and marketing practices to gain competitive advantage. PEE interprets the current and future challenges the industry faces and enables pharmaceutical professionals to overcome them with cost-effective, time-saving solutions.

Editor
Julian Upton
jupton@advanstar.com

Editor-in-Chief
William Looney
wlooney@advanstar.com

Sales Operations Managers
Claire Rice
crice@advanstar.com

Barbara Williams
bwilliams@advanstar.com

European Sales Manager
Debbie Taylor-Higgins
Tel. +44 1244 629 318
dtaylor-higgins@advanstar.com

US Sales Manager
Bill Campbell
Tel. +1 847 283 0129
wcampbell@advanstar.com

Group Publisher
Russ Pratt
rpratt@advanstar.com

Published by:

ADVANSTAR

Advanstar Communications (U.K.) Ltd
Bridgegate Pavilions, Chester Business Park,
Wrexham Road, Chester, CH4 9QH, UK

US Corporate Office
641 Lexington Ave., 8th Floor
New York, NY 10022-4503