Pharmaceutical Executive
Global Digest

May 2013
www.pharmexec.com

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# Six Side Effects of India's Glivec Ruling


William Looney

**William Looney lists six 'side effects' of the decision by India's Supreme Court to deny a patent for Novartis' top-selling oncologic drug Glivec.**

## Patenting is a political act

Technical details of patent law aside, the Glivec ruling highlights the most contested issue in medicine today: what constitutes true innovation in an age where scientific advances are transforming the very definition of a drug? This is a question that extends far beyond patent law into basic value judgments like how society should spend limited resources on medical technologies, in a way that balances patient access with the economic incentives needed to seed their development in the first place. The external demand for value — the pressure to prove it beyond doubt — is driving every aspect of the pharma supply chain today. Seeking to raise the bar around the basic patenting criteria of novelty, non-obviousness and an innovative step, as the Glivec decision just did, is but one expression of this broader challenge facing the industry.

India has made a choice — on Industrial Policy grounds. What is interesting about the 112-page court judgment is not the cursory review of whether Glivec's chemical reactant composition delivered an "enhancement of known efficacy" — a requirement for recognition as a patentable innovation — but the emphasis it places on broader issues of policy and economics. The ruling quotes approvingly from the academic literature that "rules and regulations of the patent system are not governed by civil or common law but by the interest of the national economy." More than a third of the text traces the rise of the domestic drug industry, noting that "development of the bulk drugs sector is the most important achievement of the pharmaceutical industry in India," an outcome it said was made possible by the absence of full patent protection for pharmaceuticals prior to completion of the country's accession to the WTO TRIPS agreement in 2005.

**What is interesting is not the cursory review of whether Glivec's chemical reactant composition delivered an "enhancement of known efficacy" but the emphasis it places on broader issues of policy and economics.**

## A finding writ backwards

The Court's reasoning is rooted in a complacent approach to the dynamics of market growth and social change, to wit: reproducing other people's drugs is a business model that works for India; preservation of the generic sector's license to operate has been in India's economic interest since confederation, and patent law should simply mirror that commitment. Left unsaid is whether a court of law is competent to make such assumptions on the basis of past history when the Indian industry itself is undergoing a significant shift toward greater global engagement, with innovation — in process as well as products — emerging as an equally attractive alternative to copying. India's burgeoning, up-from-nothing CRO sector is one domestic constituency unlikely to plot new growth from the Court's arguments. Another likely casualty is the rich infrastructure that surrounds modern drug innovation, from clinical trials, subsidies to academic teaching hospitals, to advanced manufacturing and improvements in

supply chain technology. Much of this investment is likely to continue to transit to more predictable host countries — like China.

## No alms for the poor

Nothing in the Court ruling suggests that the plight of those without access to essential medicines will improve. The decision simply maintains the status quo for Indian generic producers, most of who manufacture primarily for export — because the money is better abroad than at home. As the world's largest exporter of bulk drugs, Indian producers bear some responsibility for a recent World Health Organization (WHO) survey that found prices for even the lowest-priced generic products sold through the private sector were at least nine to as much as 29 times higher than the agreed international organization reference price, in most WHO regions. Even in the public sector, provision of essential generic medicines covers only about 42 per cent of the potential target population in developing countries. Access to medicines is complex — it is a cliché that bears truth. Generic production, particularly for profit, will not by itself deliver what the Court ruling claims is the commitment underlying India's patent law to "provide drug access to the rest of the world."

## Regional trade is the next phase in the activist war on patents

The Glivec case has shredded much of what was left of the industry's multilateral IP agenda, a decline that started with CEO acquiescence to the November 2001 WTO Doha Ministerial Declaration on TRIPS and Public Health. The Declaration, whose principles are embedded in the 2005 Indian patent law, limited the scope of drug patents where public health considerations intervene and thus had the effect of inhibiting enforcement of relevant TRIPS provisions. In response, Big Pharma has moved aggressively to shore up IP protection in key regional trade negotiations, including the pending Trans Pacific Partnership (TPP). As in any political negotiation involving countries at different stages of development, the high profile given to the Glivec case has put the industry on the defensive in its drive for more uniformity in the standard of protection. Operating on multiple fronts, activist groups intend to promote the Indian model of "IP flexibility" to allow for compulsory licensing, patent linkage, open pre-grant opposition and a low bar on data protection.

**More pressure on governments to sit down and negotiate structurally sound tiered pricing arrangement can obviate the need to misapply patent law for pricing and cost containment purposes.**

## Industry strategy needs a re-think

The Glivec case suggests there is not much heft left to Big Pharma's reliance on insider lobbying and technical expertise to defeat the anti-patent access lobby and governments who apply IP as a discriminatory trade barrier. Recovery must start with a better message. If what the industry describes as India's patent "theft" can be justified by activists as providing more access to the poor, then most observers will say it is a vice that is easy to live with — especially when the top five Big Pharma patent holders are currently sitting on an idle cash pile of nearly $70 billion.

Work underway in Africa to highlight how IP promotes civic engagement and job-creating entrepreneurship can break the perception that patent rights are a zero sum game, an instrument of power that hoards knowledge rather than liberates it. More pressure on governments to sit down and negotiate structurally sound tiered pricing arrangements, with proper safeguards, can obviate the need to misapply patent law for pricing and cost containment purposes. Creative use of licensing can be a "win win," with many examples evident in the HIV space. It's also worth explaining how the science of drug discovery is changing, where companies — big and small —must collaborate to mitigate the risks from the evolution of knowledge as a "floating asset." Patents are a force multiplier — it's the best solution to the "tragedy of the commons" that plagues many well-meaning drug development initiatives by taking too long to consummate and that often yield little actual value to patients.

# India: The Cost of Weakening IPRs

**Following India's decision on Novartis's Glivec, Helen Disney asks, is the country still attractive to investors and innovators?**

India's track record on intellectual property protection is a mixed one to say the least. While these days everyone is excited about the vibrant economic growth and market opportunities presented by the countries known as the BRICs, India's stance on IP — such as the use of compulsory licensing and the setting of recent legal precedent on patents — does not necessarily suggest that the country is quite as attractive to investors or to innovators as the media frenzy about India's bright economic future may suggest.

To give a concrete example, on April 1, India's Supreme Court denied an appeal challenging the rejection of a patent for Novartis's cancer drug, Glivec. The drug is a life-saving medicine for certain forms of cancer, patented in nearly 40 other countries, including many which are not noted for the strength of their intellectual property rights, such as China, Russia, and Taiwan.

Critics of the IP system have hailed this decision as a victory for patients and as likely to improve access to the medicine. In fact, although it should be acknowledged that there are some patients who struggle to access the medicine, the majority (90%) of patients currently taking Glivec in India will continue to receive the drug free of charge through corporate Oncology Access programs. Yet the consequences of the ruling are damaging for India's economy as well as for the process of creating other life-saving treatments, which future patients may need.

**India already has one of the lowest levels of clinical trials per capita... This is likely to worsen as a result of the Supreme Court decision...**

As pointed out by Adriana Benedict in a recent Harvard Law blog, the ruling will now

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force the Indian Patent Office to follow the Supreme Court's interpretation of increased efficacy as meaning increased therapeutic efficacy. This is a particularly important point when it applies to certain types of medicines whose effectiveness relies on compliance from patients. For instance, having a drug available in tablet form, even if it is not more therapeutically efficacious than an older injectable drug, would still be preferable for patients who require daily doses.

Even before the current ruling on Glivec, India already had a low level of intellectual property protection, and not just for pharmaceuticals. According to Measuring Momentum, an index of the strength of national IP environments published last year by the US Chamber of Commerce's Global Intellectual Property Center, India had the lowest overall score of all the countries measured, including the other BRIC nations. It scored only 6.24 overall compared to 23.73 for the US, which was the leading country in the Index, and 11.17 for Russia, 9.57 for Brazil and even 9.13 for China. India also received the lowest score in the specific category of "patents, related rights and limitations", although it does slightly better than China and Russia when it comes to enforcement of IPRs.

A country's IP environment is known to be important for trade, investment and economic development. Indeed, a growing body of academic and policy research now emphasizes the link between economic growth, technology transfer and stronger IPRs. OECD research, for example, has found strong links between IPRs and FDI, R&D and economic expansion. And IPRs have particular importance to the field of biomedical research, so the Indian Supreme Court's decision, along with other related factors, is now likely to make the country a less attractive prospect for future bio-medical investment.

According to research conducted by the Pugatch Consilium group and published in Scientific American, India demonstrates a limited ability to compete with other countries for biopharmaceutical investment, based on a range of measures including scientific capabilities and infrastructure, clinical environment, manufacturing and logistics, regulatory framework, healthcare financing and overall market conditions. As compared to Denmark, the most competitive country surveyed (scoring 83.2), India scores only 67.3 points on the index, putting it below Israel and Poland.

A complementary piece of research shows that strong IPRs encourage pharmaceutical R&D and investment as measured by clinical trials. Based on a study published in the Journal of Biotechnology, India already has one of the lowest levels of clinical trials per capita, falling below South Africa, the Philippines, China, and Chile and well below the UK and USA. This is likely to worsen as a result of the Supreme Court decision, which weakens India's IPR environment still further.

The trend towards a weaker legal framework for IPRs in the life sciences is not confined simply to Asia either. Even Canada, a developed Western country which one might be forgiven for assuming would strongly support the existing patent system, has been making waves over the last decade, with its IP jurisprudence lagging behind the US and Europe. According to a paper published by the Washington Legal Foundation, a legal policy institute, Canada's emphasis on proof of utility at the time of filing a patent means that applicants cannot reliably predict what information they will need to establish their claim. This creates greater uncertainty and is likely to discourage future innovation.

**Weakening IPRs, as India is now doing, will not help alleviate that poverty in order to provide more public funds for poor patients**

Put together, the Canadian and Indian examples raise a more fundamental point about the balance between supporting long-term innovation and achieving short-term value for money to payers when public money is tight (both in the West — in relative terms — since the financial crisis and in developing countries, where a much smaller proportion of GDP is given over to healthcare than in developed countries like the USA).

South Africa too is overhauling its patent laws in a highly politicized environment surrounding the need for better access to HIV medicines. Rob Davies, the country's Minister of Trade and Industry, speaking at a recent IP forum (which was picketed by activists) said there was a need for South Africa's IP policy to balance "the rights of innovators and the rights of humanity".

The simple equation promoted by activists is that high prices on patented drugs deny the poor access to medicines. This provides a morally compelling argument and a nice sound bite, but the reality is that weakening IPRs, as India is now doing, will not help alleviate that poverty in order to provide more public funds for poor patients. Nor will it help India to become a place where it can create the innovative medicines of the future.

# Is Indian Pharma Growth Doomed?

**Will India's regulatory failures doom the future growth of its pharmaceutical industry? Chris Ward of World Health Advocacy reports.**

Indian pharmaceutical companies' profits have grown hugely in recent years, largely due to the sale of generics to the US and EU markets. But, with the next wave of drugs coming off patent in the West set to stretch the Indian pharmaceutical industry beyond its limits, predictions for continued growth are likely to prove wildly optimistic.

Contrary to claims that India's robust generics industry is driven by the noble goal of being 'the drug store for the developing world', overwhelmingly the growth of the industry is through sales to established country markets in the US and Europe.

Indeed, during 2012, Dr Reddy's sales to the US soared by 133%, increasing net profits by 88% and making US sales 44% of the company's total sales. Similarly, Lupin's US sales grew 63% and Sun Pharma's 104%, while Indian pharmaceutical major Wockhardt reported a 95% increase in consolidated net profit, largely driven (71%) by sales to the US and the EU.

**Contrary to claims that India's robust generics industry is driven by the noble goal of being 'the drug store for the developing world', the growth of the industry is through sales to established markets in the US and Europe.**

The catalyst for the recent robust growth for Indian companies in these markets has been the 'patent cliff', a phrase used to describe the expiry of pharmaceutical patents on a range of drugs over a short period of time. The patent cliff reached its zenith in 2012 when patents expired for drugs valued at just over $35 billion in annual sales. This opened up the market to generic manufacturers in countries such as India, which were able to take a significant amount of market share from the original drugmakers, thereby improving their own profits.

Some industry watchers believe that the windfall profits from the patent cliff phenomenon are set to continue over the next three years as more drugs come off patent, growing 20% over 2012 levels in 2013, and culminating in 2015 when the value of patent expirations reaches more than $30 billion, approaching the record of more than $35 billion set in 2012.

But these predictions reflect a misunderstanding of the nature of the next wave of drugs coming off patent and ignore the fact that the chaotic drug regulatory environment in India makes it highly unlikely that companies in the country can produce follow-on biologic drugs that would be approved for use in developed markets.

## The patent cliff windfall: why Indian manufacturers' profits soared in 2012

In 2012, Indian manufacturers such as Ranbaxy, Sun Pharma and Lupin seized the opportunity created by the regulatory circumstances in the US, as well as the nature of the drugs coming off patent, which were largely small molecule blockbuster drugs with high sales volumes and low production costs, to significantly boost their profits.

There were three key reasons for their success. Firstly, Indian generic manufacturers were able to leverage both


the fact that their production facilities were FDA accredited and that their expertise in reverse engineering originator products was well established.

Secondly, by being the 'first to file' for generic approval by the FDA for sales in the US market they benefitted enormously from the six months of market exclusivity that is given to the first generic entrant into the US. They were therefore, for a short period of time, able to dominate the market at comparatively higher prices without competition from generic competitors.

And finally, unlike in India, where public confidence in the regulation of drug quality is very low, US consumers are confident in FDA regulatory oversight and accept that FDA-approved generics will be bioequivalent and interchangeable with the original product. Indeed, in 2011 in the US, generics were dispensed 94% of the time when a generic form of the drug product was available, while, in contrast, those in India able to afford them insist on originator branded generics because the brand is a proxy for quality.

Of course, US regulations on generic drugs mean Indian companies can only benefit significantly from patent expirations in the short term. Take Ranbaxy, for example. At the end of 2011 the company received approval to launch the first generic version of the blockbuster drug atorvastatin (generic Lipitor). Armed with six months of market exclusivity and manufacturing capacity in India and elsewhere, Ranbaxy generated nearly $600 million in sales over a six month period from this single product.

However, following the expiration of market exclusivity and the onset of competition from other generic producers, analysts estimated Ranbaxy's sales of atorvastatin to tumble to $60-65 million. The drop in the company's share in sales of the drug in the US market further escalated after the November 2012 recall of 41 batches of the product.

This scenario among major Indian generic pharmaceutical manufacturers will continue through 2013: sales from first entry generics will initially be robust but will quickly evaporate when the six month period of market exclusivity expires.

## From blockbusters to biologics: the changing nature of drugs coming off patent from 2013

More significantly for the Indian pharmaceutical industry, however, the product mix coming off patent over the next three years is dramatically different to the small molecule blockbuster drugs

that dominated patent expirations in 2012.

Beginning in 2013 and continuing through to 2015 many of the blockbuster patent expirations are biologic drugs. Indeed, in 2015 biologics will constitute nearly one third of the drugs coming off patent, with a market value of $10 billion. Unlike the high volume low production cost small molecule generic drugs of 2012, biologics are low volume high production cost products, and more importantly, small molecule generics are bioequivalent to originator products whereas generic biologics or biosimilars are not.

The importance of this difference cannot be overstated. In contrast to small molecule drugs, it is difficult and costly to demonstrate that a generic biologic is interchangeable. Small molecule drugs are inexpensive to copy because there is no requirement on the generic manufacturer to prove the safety and efficacy of the generic copy through clinical trials. But with biosimilars, this requirement does exist, as the safety and efficacy of a biosimilar is highly dependent on the method of manufacture and formulation, with minor differences potentially resulting in serious consequences.

This was demonstrated by the 2012 meningitis outbreak in the US that killed 33 patients and caused serious illness in 450. Although the outbreak was not caused by a biosimilar, it did clearly demonstrate the potentially disastrous impacts of contamination. Indeed, following this event, Dr Bert Petersen of the New York University School of Medicine argued that the circumstances surrounding this tragedy should be instructive for guiding the future of biosimilar safety: "The difference between biologics and conventional medicines is that the latter are made from chemicals and have known structures, whereas biologics and biosimilars tend to be heat-sensitive, can become easily contaminated by microbes and small changes in their structures can lead to unexpected or even harmful effects in patients," he explained.

**There is little or no opportunity for dramatic and immediate market penetration in biologics in established markets such as the US and Europe,**

Essentially, small molecule drugs are made from chemicals and have simple and well-defined structures, whereas biologic drugs are produced in living cell cultures and tend to be unstable and difficult to control. The most important result of this for patients and physicians is that it is impossible to ensure that a biosimilar is an identical copy of the original product.

Therefore, the vast majority of US physicians (85%, according to a recent survey) would be reluctant to switch their patients from an originator biologic drug to a biosimilar. And, even more significantly for the Indian pharmaceutical industry, to date no interchangeable biologic drug has ever been approved in the US.

## Biologic bonanza: the consequences for Indian manufacturers

This new set of circumstances will have significant consequences for Indian generic manufacturers. Firstly, there is little or no opportunity for dramatic and immediate market penetration in biologics in established markets such as the US and Europe, and, secondly, although markets will exist for new patients in emerging economies, the significant production costs of biologic generics will shrink margins.

Although India has announced a pathway for biosimilar approvals there are currently major impediments to India becoming a leader in this field, not least competition, particularly from South Korea, which is currently the global leader in biosimilar development in terms of trials and drugs in the pipeline.

Moreover, in order to penetrate the biosimilars market, a manufacturer must clearly establish the safety and efficacy of its product, a process which requires strong clinical research capabilities including clinical trials. Yet, the recently released pathway for biosimilar approvals in India lays out a number of circumstances under which the requirement for a clinical trial will be waived.

With limited or, in some cases, no clinical trials for Indian biosimilars it is difficult to contemplate the uptake of Indian biosimilars in developed markets such as the US and Europe, which have more rigorous standards than those in India. Physicians will not risk prescribing them and patients will not risk taking them without proof of safety and efficacy.

The greatest challenge for India is its weak and chaotic regulatory system. India has, in fact, developed some follow-on biologics that are being marketed in India without the benefit of a strong pharmaco-vigilance regime. But outside of India, these products are not approved and therefore will only be available in unregulated "grey" markets and not for use in lucrative developed markets. Recognizing these challenges many major Indian pharmaceutical companies

have established joint ventures and partnerships with foreign multi-national research-based pharmaceutical companies. (see chart)

While Asia's third largest economy is blessed with a highly educated population and world-class expertise in manufacturing quality pharmaceuticals, it lacks the capacity to provide the oversight and regulation that biologic medicines require.

**India's trivializing media, ineffective policy making, and inadequate regulatory system may well doom its pharma industry to merely a minor role in the future development of biosimilars.**

Indeed, the industry has already come under fire this year due to a high profile case in the Supreme Court between the regulator and health activists, who allege that companies have used poor people as human 'guinea pigs' to trial unsafe drugs without their knowledge or consent and without proper state scrutiny. This current lack of rigorous regulation in India makes it all but impossible to conduct clinical trials, which are an essential pre-requisite for developing a biologics drug industry that can supply biologic medicines to highly regulated developed markets.

India possesses many competent world-class researchers and its pharmaceutical majors are more than capable of producing top-quality generic blockbuster drugs. However, its trivializing media, ineffective policy making, and inadequate regulatory system may well doom its pharmaceutical industry to merely a minor role in the future development of biosimilars. While companies such as Ranbaxy, Dr Reddy's and Sun Pharma will continue to play an important role in the global pharmaceutical sector, the best days for the Indian pharmaceutical industry may already be behind it. For India the 'patent cliff' will quickly become the 'patent wall' as biologics are set to dominate patent expirations in the years to come.

## About the Author

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# Patently Excited

**It's exciting times for patents in Europe. Not everyone's excitement is pleasurable, but there's certainly plenty going on, says Reflector.**

Much of the excitement is linked to the imminent advent of Europe's first real European patent. After decades of failed attempts, by the beginning of 2014 the European Union will finally have a 'unitary patent' — a system offering a single patent valid across all the member states (or nearly all — two member states have been more excited about the prospect of sabotaging it). For its many supporters, the unitary patent offers real advantages. Probably faster, certainly cheaper, and very much easier to manage than the patents available under the current patchwork of patents granted by national authorities or patents granted by the European Patent Office and requiring subsequent national validation.

The attractions are evident of securing a patent across most of Europe for just €4,725 instead of the €36,000 it typically costs today, and being able to obtain it with a single application, and just in English, French or German (instead of multiple applications or validations subject to local language rules). In addition, it will be backed by a new international court specialized in patents, empowered to give rulings rapidly, and across every country where a patent is disputed — instead of parallel litigation in national courts leading to inconsistent rulings.

The "sabotage" attempts came from Italy and Spain, the two member states that have consistently held out against a Europe-wide system, largely because they feared negative effects on national innovation from the exclusion of their languages from the new system. They mounted a challenge at the EU's own court against the creation of a mechanism they object to. But the court threw out that claim in April, ruling that the 25 countries could lawfully go ahead with their plan — particularly since Spain and Italy are free to join it if they so choose.

Even so, there are concerns about how the new system will work in practise. For all the simplicity of the underlying concept, its implementation is necessarily complex. As lawyers and accountants working for the innovative drug industry probe the detail, there is still a lack of clarity about precisely what it can and cannot do, and precisely how much it will cost.

There are concerns among generic manufacturers too. They do not want to see easier patent protection resulting in increased limits on competition. That, they argue, could have a perverse effect on the EU's sacred principle of a single market — or internal market, as the jargon terms it. The European Generic Medicines Association is anxious to secure fair competition, and to ensure that generic companies have a voice in decisions on disputes with originators "without compromising legitimate enforcement of patent rights."

So between now and the start of next year, a fever of expectation will be matched by a feverish search by all sides to get the best out of the new system. Meanwhile, alongside the moves on the unitary patent, further excitement is sweeping through the world of intellectual property over broader questions of just who should be making decisions on what a patent can and cannot do. Mirroring in some ways the issues raised by generic drug firms, this is emerging as an institutional battle between competition authorities and patent authorities, and it is taking place simultaneously in Europe and in the USA. It goes much wider than the drug industry, as demonstrated by recent decisions by the EU competition authorities questioning the scope of mobile phone patents. But the consequence is that, by a fine irony, just as getting a patent is about to get easier in Europe, hanging on to it may be getting harder.

Plenty of excitement still to come!

Getty Images/iStockphoto

# The Box of Delights?

**Are the answers to the UK's pharma sector problems to be found in the Patent Box? Julian Upton reports.**


Julian Upton

April 1 saw the activation of the UK's much vaunted 'Patent Box', which introduces a lower rate of corporation tax on profits generated from UK-owned intellectual property. Under the scheme, businesses will pay just 10% tax (as opposed to 23%) on any profits arising from patents newly commercialized in the UK.

Proposed by the previous Labour government as a measure to strengthen the UK's 'knowledge economy', the scheme's tax break extends to royalty and milestone payments and also sees the introduction of a special 10% rate of R&D tax credits.

The scheme has not been without its critics. According to law firm Latham & Watkins, it is "over complicated, subject to numerous limitations and … unlikely to result in a significant influx of intellectual property into the UK." And Tony McKenna of the New Statesman questions, from an admittedly anti-corporate perspective, the theory that the scheme will provide impetus for companies to conceive "fabulous new technologies, and give a spurt to growth and development". Instead, he points out, companies do not actually have to own the patent in order to attain the tax break, they can simply lease it from the original patent owner. As a result, there is no real incentive to innovate "in house".

**There are wider fears that cuts and increased globalization will continue to weaken the UK industry**

McKenna's biggest gripe, however, is that the Patent Box is just a dressed-up tax avoidance scheme, an "opportunity for corporations to achieve massive, unwarranted tax slashes on their products".

## Pro-pharma?

The 'tax dodge' angle is not likely to upset pharma too much. Indeed, there is little doubt that the UK pharma sector will be the Patent Box's principal beneficiary. Latham & Watkins predict that the scheme should be successful in deterring pharma and biotech companies from migrating IP out of the UK, and say that the nearly-£1 billion (USD$1.5 billion) revenue loss that the scheme's introduction will cost the government represents "a significant windfall" for the sector. Indeed, as soon as the scheme's introduction was confirmed in 2012, GSK announced a new £500m investment in the UK, the construction of its first new facility in 40 years and the creation of 1000 jobs (in Ulverston, Cumbria).

But there are wider fears that cuts and increased globalization will continue to weaken the UK industry. The Financial Times (April 21) suggested that, while tax incentives are welcomed, "governments can only tinker around the edges" and pointed to warnings that, without "more active intervention", UK drugmakers "risk decline akin to that of the car industry in the 1980s". The report also echoes arguments that there are still significant weaknesses in the sector (in areas such as translational medicine) that need to be addressed with the creation of new therapeutic centres of excellence that combine the best of academia and industry.

Only time will tell if the Patent Box will become the saviour of the UK pharmaceutical industry. In the short term, though, there is no question that its introduction will prove an immediate boon to one group of professionals — the patent lawyers.

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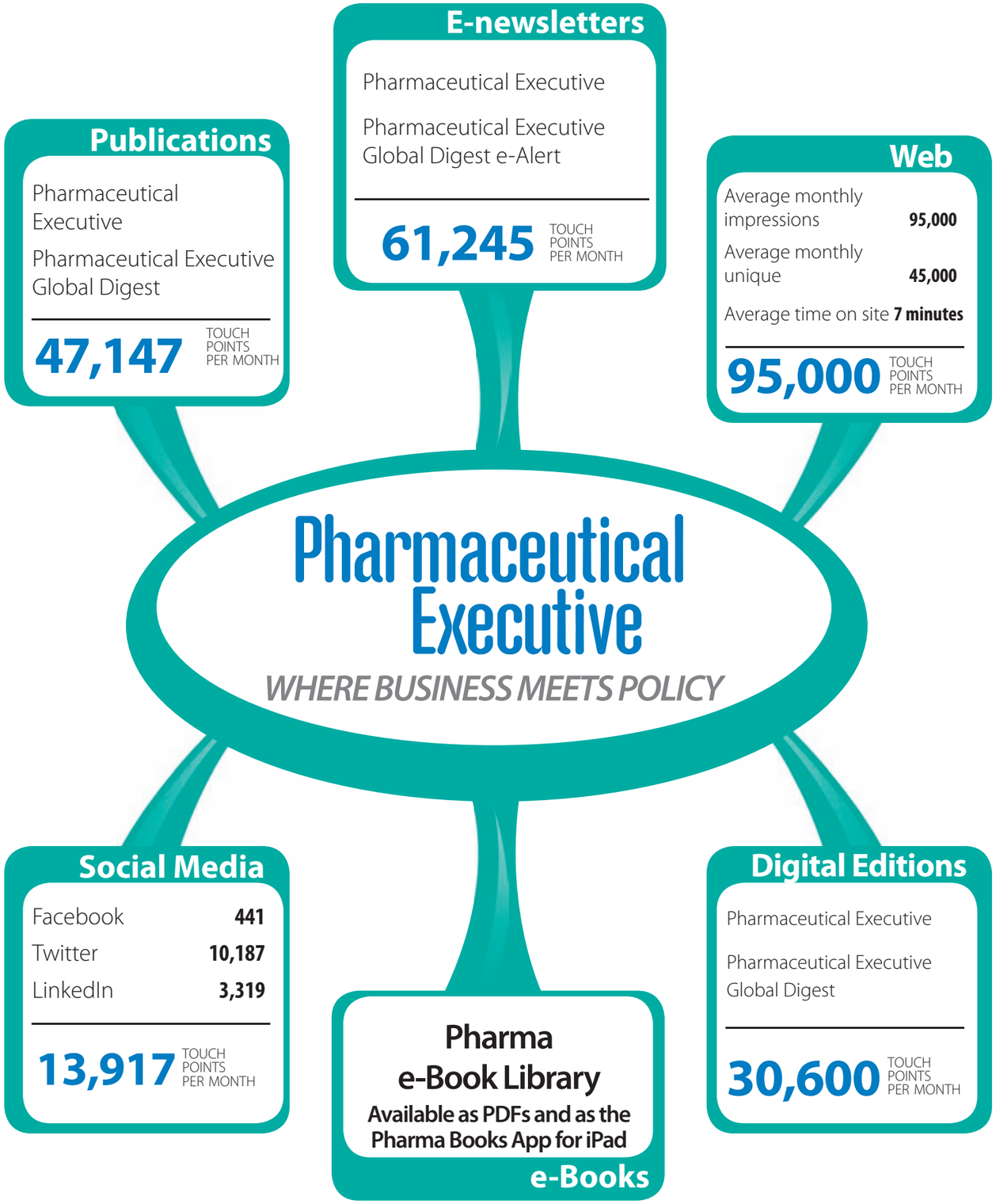


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| Contract Services | 10,236 |
| Consultant | 5,825 |
| Marketing Communications *(including advertising & PR agencies)* | 4,498 |
| **TOTAL UNIQUE SUBSCRIBERS** | **90,929** |

| FUNCTION DIMENSION | QTY |
|---|---|
| Business Development | 3,797 |
| Consultant | 3,197 |
| Corporate Management | 26,711 |
| Finance | 1,403 |
| HR | 815 |
| IT | 1,851 |
| Managed Care | 2,920 |
| Market Research | 1,218 |
| Marketing | 12,913 |
| Media Planning | 1,375 |
| Medical Affairs | 4,860 |
| QA/QC | 7,201 |
| R&D | 16,386 |
| Regulatory Affairs | 2,651 |
| Sales management | 7,771 |
| **TOTAL UNIQUE SUBSCRIBERS** | **90,929** |

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# A New Era for NICE

**The UK's NICE has not only survived the sweeping reforms that are changing the country's health service, but has emerged with in a stronger and arguably more controversial position. Leela Barham speculates on its future.**

David Sutherland/Getty Images

With the reforms to the NHS in England going live on April 1, 2013, the National Institute of Health and Clinical Excellence became the National Institute of Health and Care Excellence. The change of name signals the role of NICE not just in health, but now also in social care. It's also coincided with a new Chair, Professor David Haslam, replacing Sir Michael Rawlins.

Now NICE has to produce quality standards for social care. This is in addition to the myriad other work undertaken by NICE ranging from public health guidelines to the very widely known (in part because that's technology appraisals outnumber all other forms of guidance with the exception of interventional procedures), and often controversial, technology appraisals.

The question still remains though: is NICE actually delivering on its core remit to tackle unwarranted variation in availability and quality of NHS treatments and care across England? Perhaps a question worth returning to by Government.

## Stronger statutory footing

The change of name isn't the only major change affecting NICE. NICE is now a non-departmental public body (NPPB). This puts it onto a firmer statutory footing and also gives NICE more independence from Government, with provisions in the Health and Social Care Act (2012) that stop either the Secretary of State or NHS England (previously known as the NHS Commissioning Board) giving NICE directions about the "substance of advice, guidance or recommendations".

## Is NICE actually delivering on its core remit?

The relationship between NICE and the Department of Health (DH) under these new arrangements are to be set out in a Framework document, anticipated to be finalized by May following discussion within NICE, and changes from the Department of Health and HMT.

NICE is also to produce a Charter, to set out the functions of NICE and how it will use them. The first draft went to NICE's Board on the April 8 to discuss and sets out the role of NICE and their broad ways of working. Industry will be interested in the section relating to how NICE works with health care industries. NICE say "Much of what NICE does has an impact on the healthcare industries that supply the NHS. We are very conscious of the responsibility we carry when we advise the NHS on the use of health technologies and we know that what we say about new technologies is often taken into account in health systems beyond the United Kingdom. For these reasons we regard the relationship we have with industries and individual companies as having equal importance with our other stakeholders and we will continue to work with the industry associations in this country and abroad to build mutual respect and trust."

## NICE to do the 'V' in VBP

Back in March 2013 the DH made it clear in their response to the Health Select Committee Inquiry into NICE that NICE has 'a central role in the value based pricing system, including in undertaking an assessment of the costs and benefits

of different medicines', and will be responsible for 'the full value assessment of medicines under the future system'.

The greater independence of NICE from Government, and at the same time, it's responsibility for the full value assessment raises questions about how that will work exactly. Including how to challenge NICE's approach and recommendations because even under the current arrangements opportunities differ whether it's a Single Technology Appraisal versus a Multiple Technology Appraisal. At the same time, it could also be an opportunity to take a fresh look at how NICE does their assessment and appraisal now, and make improvements that fit with the ethos of the value assessment part of VBP. That includes taking wider societal perspective and more account of innovation. Although that would be rushed; there isn't long until the go live date of January 1, 2014, for VBP.

In the same breath the DH also say that with NICE doing the full value assessment that there will be no additional data burden on companies. Implying before NICE has even got going, that they'll be expected to follow policy decisions made by the DH, which is right and proper, but also to a degree follow a methodology handed over to them. Not only that, but the DH will set the weightings for components in that value assessment. That also implies a worrying prospect of a formulaic approach and perhaps not enough deliberation when wrestling with real life decisions of when to use what technology for real life patients.

It will probably be a source of relief to many that the DH also make it clear that the price resulting from the value assessment will be subject to negotiations between industry and Government as they work out the successor to the Pharmaceutical Price Regulation Scheme (PPRS).

## The future

NICE was already one of the few agencies to stay in the reforms of the NHS in England. Now it's also on a stronger basis with arguably an even more controversial role to determine the full value of new medicines. Although NICE hasn't been set a role in pricing, that value assessment will link to the price that the NHS will pay (assuming that a price can even be agreed between the DH and companies) also ensures even greater interest from patients, industry and media in the work of NICE.

# “Sunshine” Tip of the Iceberg


Jill Wechsler

**There seems no end to demands for data on clinical research, conflicts of interest, company payments, and drug prices. Jill Wechsler reports on pharma’s journey to full disclosure.**

Although recent legislation and regulations have greatly expanded the range of information that pharmaceutical companies have to unveil to the public, there’s an escalating demand for even more transparency.

The new “Sunshine” law — requiring drug and medical device companies to report virtually every penny they transfer to physicians and teaching hospitals — is just the tip of the iceberg.

The theory is that disclosure of financial relationships between manufacturers and prescribers will shed light on medical treatment decisions — particularly for new, more costly medicines versus older, cheaper treatments.

This call for greater data transparency reflects charges that sponsors have hidden important safety information from regulators and the public. Pharma companies counter that full disclosure can raise patient privacy issues and lead to misinterpretation of findings by non-experts. Yet, a number of pharma companies are adopting a full disclosure policy, some building on research disclosure requirements set in consent agreements negotiated with the Department of Justice and other federal and state enforcers.

## Price transparency

An equally important goal of US transparency advocates is to reduce healthcare spending through competition generated by broader disclosure of prices for healthcare services and medical products. The new online “marketplaces” established by Obamacare for consumers to shop for health insurance will feature comparative information on plan premiums, co-pays, and benefits, along with drug formularies and pharmacy coverage policies, to help identify the best deal for an individual on coverage and costs.

Disclosure of information on drug coverage and costs has gained support from a steady supply of reports on pharma pricing issues from federal investigators. Consumer advocates and pharma critics maintain that full disclosure of drug prices will lead to much lower costs for patients. Pharma companies counter that such transparency will only boost prices overall, especially for those customers that currently enjoy favorable rebates and discounts. Industry’s biggest fear is that some kind of national formulary will lead to reference pricing, higher rebates, and eventually drug price controls.

## Social media exposure

Over the long run, though, much information on pharma research and prices will become public with the expansion of global search engines able to tap into millions of queries and postings on medical treatments and healthcare costs. A recent study by scientists at Microsoft Research, Stanford, and Columbia University, published in the Journal of the American Medical Informatics Association (March 6, 2013), found that Internet searches on drug use uncovered previously unrecognized adverse events. Here, queries from six million people in 2010 searching for information on antidepressant Paxil and cholesterol treatment Pravachol disclosed a greater incidence of high blood sugar in patients taking the two drugs.

It’s not hard to imagine similar analyses of consumer searches for lower drug prices, product safety reports, and complaints about pharma marketing and advertising from health professionals and the public.

The ultimate question is whether such disclosure enhances patient care — or adds to the complexities of innovative research.

Jill Wechsler is Pharm Exec’s Washington correspondent.

# Catch On to Content Marketing

**Pharma should have a head start in the content marketing race, but familiar fears are holding it back, writes Peter Houston.**


Peter Houston

You know this: digital marketing means you have the potential to get your message in front of more people than ever before; search and social media offer reach on an unparalleled scale. According to global internet analytics firm Comscore, there are 13.7 billion searches conducted on Google every month. With 60% of US consumers saying they looked for health information online in the last year, that's a lot of potential patients.

The problem is, that reach is available to everyone else from Top 10 pharma to your local Deli: We're all publishers now.

Actually we're not all publishers, we're all authors. Publishers — certainly in the traditional sense of the word — would never allow most of the content on the Internet out of the slush pile. And it's the public accessibility of that slush pile that might just provide pharma with its best opportunity to be heard above the noise.

Content marketing — the art of creating and distributing relevant and valuable content to attract, acquire, and engage a clearly defined and understood target audience — is being hailed as the brightest hope for marketers desperate to cut through the Internet's clutter. So far so good — pharma has been producing quality, expert-led, evidence-based content for ever.

What is new is the importance marketers are placing on real value delivered through content. Possibly the biggest reason for this new focus on quality is that Google, the daddy of web search, got tired of people gaming its search algorithms with sub-standard content.

To combat SEO tactics that had more to do with keyword stuffing than content quality, Google changed the rules of the game with its Penguin algorithm, introduced this time last year and already headed for its third update. I won't even begin to pretend to understand how Google's algorithms work, but I do know they are focusing more and more on the quality and 'shareability' of content to improve the search experience and this puts content marketing firmly in the frame.

There's also the added benefit that, rather than interrupt people with unwanted sales pitches, content marketing offers a non-interruptive approach to customer communication. The ideal is to create a regular stream of valued, trusted content that customers will actively seek out and share. Pharma's content-marketing opportunity is to make sure that when a doctor or a patient goes searching for health information — which they are doing more and more — the right content is there waiting for them. When they get exactly what they want, when they want it they're also happy to pass it on to friends and family. The problem is pharma doesn't like sharing.

Content marketing principles — valuable content that engages a clearly defined audience — might have been at the heart of pharma's efforts to help HCPs and patients understand and adopt new treatments for years. Pharma should have a head start in the content marketing race, but it's firms like Marriot, Old Spice and American Express that are getting noticed for their content marketing efforts, because they love people to share their content

"As a well-oiled content machine that knows how to build relationships, pharma should thrive in this new era," writes Dr Candice O'Sullivan of Australia's Wellmark agency on PharmaForum. "Here is an industry well used to the rigors of consistently producing high-quality content — the number one challenge for most content marketers — but finds it virtually impossible to 'share'."

O'Sullivan closes by describing Pharma as an industry "too preoccupied by the risks involved to be able to make the most of this opportunity". Sound familiar?

# Smarter Multichannel Interactions

**Jan van den Burg of Veeva Systems calls for better orchestration of multichannel communications across sales and marketing.**


Jan van den Burg

The pharmaceutical industry is moving away from a product-centric sales model toward a more engaging, customer-centric model, one that often includes supporting services 'beyond the pill.' Additionally, leveraging the growing number of communication channels available to interact with physicians is a crucial component of customer-centric selling. Multichannel activities are a highly cost-efficient part of the marketing and sales strategy and offer a convenient way to reach low-access and no-see physicians. This is all good news — but for one problem: poor choreography. Multichannel communications today are not well orchestrated across sales and marketing so busy physicians are bombarded by sometimes irrelevant communications, undermining the entire prem — of customer-centricity.

For pharmaceutical sales reps to effectively execute customer-centric strategies, they need to see the complete history of a physician's interactions with the pharmaco and fully understand their individual preferences and behavior patterns. Unfortunately today, there are gaping holes. Typically, sales reps only see a slice of all customer interactions. They rarely see marketing communications such as email, direct marketing and online detailing activity, for example, leaving reps no chance to respond, follow-up or even reference these other communications when interacting with the physician. The result is a missed opportunity to deliver a customer-centric call.

Worse still, most reps are limited to a single channel: the face-to-face meeting. What if the customer wants to receive prescribing information via email as an immediate follow up from a rep visit? What if the customer wants to spend more time exploring a complex mechanism of action in their own time, online, after it was introduced by the rep?

The key is bringing together the interaction data gained from all channels in a single solution so that both sales reps and marketing teams have complete visibility of all customer interactions. New cloud-based technologies have emerged that are finally empowering reps and marketers with increased visibility and the additional built-in channels they need to engage with customers. It's a holistic approach to customer relationship management with a more complete view of customer interactions across channels like direct marketing, third-party web portals and email. All of the information can be viewed in one place, centered on one customer and in one system that's easily accessible through the cloud.

With access to the entire history of interactions, both reps and brand teams are then equally armed with complete information about customer preferences to ensure that customers receive the content they want on their terms. Key messages can be delivered on a mobile device to view between appointments, tailored for the iPad to read at home after office hours or via email to be read at lunch time. And, because the content physicians receive is now more relevant too, customers are more willing to take the time to absorb the information.

Now, when reps leverage different channels to communicate with customers, this multichannel strategy adds even more value by truly enhancing the customer experience. A well-orchestrated email introduces the personal touch and demonstrates perfect timing, for example, when sent immediately after a customer visit as a follow-up. It also helps transition the trust the customer already has in the sales rep into the digital domain as seen in the very high open rates for emails delivered by reps, especially those sent as a direct and physician-requested follow-up.

"Multichannel communication strategies aren't new. For years, the life sciences industry has been investing in various channels, intent on providing customers with the information they need," says Eric Newmark, program director for IDC Health Insights. "Unfortunately, the customer

interaction information has been locked in different systems designed to execute across each different channel individually," he adds. "For multichannel to truly be powerful, sales and marketing need a combined, single view of the customer to deliver a seamless and coordinated customer experience."

## Actionable insights

For too long, pharmaceutical companies have embarked on multichannel by spreading their proverbial eggs in many different and stand-alone communication baskets. As a result, they not only miss out on the opportunity to properly choreograph customer interactions between sales and marketing but they also miss out on the greater opportunity to create the best customer interaction possible based on data intelligence.

Digital and face-to-face interactions supported by digital content (such as iPad detailing), allow companies to capture valuable data relating to content preference, message flow, channel mix preference, areas of interest, sphere of influence, communication behaviour and more. If captured at all today, this data usually sits in separate and non-integrated systems (including those managed by external parties), is recorded in different formats and cannot be mapped to existing customer master data. To derive intelligence from this data, therefore, is a tall — if not impossible — order. And the next step, converting data into actionable insights for an engaging and effective customer dialogue, is merely wishful thinking.

New multi-tenant cloud-based systems and platforms, however, enable multichannel data accessibility, flexibility and configurability to meet regulatory and legal requirements, including opt-in, data privacy and tracking. Information from key channels such as tablet-based detailing, email, online documentation, physician self-directed detailing and remote detailing are all part of the core CRM solution so that data is collected in a standard format for easy analysis.

Using these systems, companies can collect and analyse important data about customer interactions, enabling both sales and marketing to understand a customer's needs and respond appropriately. Each proceeding customer interaction across channels will then be consistent, relevant and timely — all perfectly composed for a successful customer-centric approach rather than just a high quantity of disjointed communications.

## What about content?

With the proliferation of channels and devices and the drive to tailor content based on customer segmentation, the total volume of content that needs to be developed increases dramatically. At the same time, this content needs to create a consistent and positive customer experience. It's a huge new challenge for pharmacos to efficiently and compliantly manage the development, distribution and use of all this highly specific content.

Advanced, cloud-based content management solutions that are integrated with a company's CRM system, however, not only facilitate efficient content development but also enable the collection and fast dissemination of data regarding content's effectiveness across markets, channels and customer segments. Combined with market research, prescription and other data sources, and both reps and marketers see the big picture so they can continuously improve their interactions with customers. Additionally, these solutions help reps get past the no- or low-access physician hurdle by enabling controlled email of approved, up-to-date promotional content — something that both European and US companies have struggled with over the years due to the risk of non-compliance.

Finally, having integrated CRM and content management provides a unique opportunity for pharmacos to bring together sales and marketing for increased customer-centricity and effectiveness. In particular, it empowers pharmacos with:

- Efficient global content sharing and re-use across markets and channels
- Integrated medical, legal and regulatory approval processes
- Publication and withdrawal of content across channels
- Full global tracking of 'where used' content to ensure compliance

## The result

Well-choreographed multichannel interactions with the customer are the key to maximising sales and marketing performance — and, the only way to fully execute a customer-centric model. Next-generation cloud-based CRM and content management applications will enable the industry to deliver additional value to the customer through smarter multichannel interactions at a more sustainable cost.

## About the Author

Jan van den Burg is VP of Commercial Strategy, Europe, for Veeva Systems.

# Events

## Global Publication Planning and Clinical Trial Registries

**Date:** June 11–12, 2013
**Location:** Dublin, Ireland.

Attend this highly anticipated forum to learn more about how professionals working in publication planning and clinical trial disclosure can coordinate data sharing to ensure transparency. To be discussed:

Results posting/disclosure on the EudraCT database and the current pilot studies being conducted in 2013; Posting results for unapproved drugs; Evolving EudraCT and Clinicaltrials.gov regulations; Emerging development of local and national registries.

For further information, visit http://www.cbinet.com/conference/pc13204

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## CBI's Orphan Drug Summit 2013

**Date:** June 17–18, 2013
**Location:** Philadelphia, PA.

Through this innovation summit, learn new and exciting ways to attack these concerns head on with sessions covering:

* How to achieve global market access while anticipating emerging regulatory policies.
* Exploration of pricing and reimbursement issues.
* Maximizing collaborations between pharma, patients, government. departments and VCs.

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* Capitalization of personalized medicine.
* The benefits of experimental trials and tailored therapeutics.

For further information, visit http://www.cbinet.com/conference/pc13190

## Annual Forum on Sunshine and Aggregate Spend

**Date:** August 19–21, 2013
**Location:** Washington, DC.

What you can expect when you join more than 375 of your peers in Washington this summer: Hear how your colleagues have interpreted the Final Rule; Discuss ways to get all of the data compiled for reporting in March 2014; Explore different strategies for data verification — How to ensure data accuracy, completeness and integrity; Participate in the annual industry benchmarking exercise; Learn from industry peers sharing real-world case studies and experiences; Contribute during peer-to-peer working group discussions.

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For further information, visit http://www.cbinet.com/conference/pc13156

# Pharmaceutical Executive Global Digest

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.

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