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Questions for U.S. pharma companies

Rx Coverage and Obamacare 2014: The "New Medical Culture"

Will the new Obamacare emphasis on preventive care actually lower healthcare costs?

Tom Norton outlines the Obamacare-related questions that are likely to be of concern to pharma companies in the U.S. this year.

It's expected that about 35 new FDA approved prescription drugs will arrive on the market in 2014. What are the chances that these new medications will be utilized by Obamacare health programs? Given that the majority of these products are likely to be high cost, specialty drugs, dedicated to small, niche markets, pharma execs should anticipate that the chances of these drugs becoming first line Obamacare prescription options are going to be relatively low.

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However, as several of these anticipated prescription drugs will address unmet needs in areas such as rheumatoid arthritis, cystic fibrosis, and various blood cancers, it's possible that they may be included in various higher end Obamacare insurance offerings.

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But, it's also very likely that the only way to access these new products will be with prior authorization approvals, and very substantial copays.

Will 2014 be the year that U.S. pharma considers revamping those fading "patient assistance plans"?

Emphasis on "preventive medicine" Rx products

Will the heightened emphasis on "preventive" medicine in Obamacare result in greater physician utilization of prescription drugs designed for the treatment of chronic conditions? And given the need for compliance, how well will the new Obamacare patients stick to their prescribed Rx regimes, including refilling those preventive medicine prescriptions when needed?

Pharm execs will need to watch the development of the various "preventive medicine" trends to ascertain how those Rx products are actually being utilized in the evolving Obamacare health insurance climate.

But probably the biggest general preventive care question of all is "will the new Obamacare emphasis on preventive care actually lower healthcare costs? " Although there is a lot of earlier medical experience to suggest otherwise, 2014 will be the benchmark year that the new healthcare program will use as it begins to prove the value of preventive medicine. It goes without saying that much is on the line for U.S. pharma as this review of preventive care starts.

Rx copay "shock"

Another huge economic factor next year is the prospect that many of the new patients who sign up for the "bronze" and "silver" Obamacare health plans are going to end up paying very substantial copays in 2014 to obtain their prescription drugs. What impact will this have on the Obamacare patients?

Will the heightened emphasis on "preventive" medicine result in greater physician use of prescription drugs designed for chronic conditions?

Although the Rx industry has managed copay challenges in the past, the anticipated extremity of these Obamacare prescription copays may shock a lot of the new program's patients. Clearly, the prepared pharma exec will have to find ways to mitigate the Rx copay surprises in 2014, and beyond.

Thinking about this, what can a pharma exec really do to assist patients who are denied access to their company's medications due to high copays in a healthcare plan? Here's an intriguing question: Will 2014 be the year that U.S. pharma considers revamping those fading "patient assistance plans" to deal with extraordinary Obamacare copays?

Lost "high prescribing" physician access

One of the clearest strategies that the Obamacare healthcare insurance plans will utilize to will be lowering the number of physicians who will be practicing in the Obamacare networks.

In the main, this will be accomplished by utilizing more community hospitals and smaller, local health centers. This means the services of thousands of physicians who practice in more expensive, urban specialty hospitals will in many cases be excluded from new Obamacare health offerings. This will be done as the fees charged at the larger,

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urban institutions charge are viewed as "too expensive" by Obamacare insurers.

Therefore, to get care, many Obamacare patients will have to "switch" to new doctors who are located outside of their home neighborhoods. They will also experience a new type of "lower cost" medicine that will be practiced by these doctors that will include a limited number of prescription drugs that are listed on highly restricted formularies.

Why is this important to the Rx industry? Because many of the brand name industry's "high prescriber/early adopter" physicians practice in those urban, specialty hospitals. Assuming these higher cost, urban physicians are discriminated against in the Obamacare system, it will mean that the general use of newer, more expensive brand name drugs could drop, and likely drop substantially.

The net result, some argue, will be a clearly defined two-tiered system of Rx care in the U.S. That is, many of the people who buy Obamacare health plans will have access to fewer, cheaper drugs and not be able to access the services of "high prescribing" doctors who use innovator drugs, while those Americans who will continue to be covered through their private employers will enjoy much more robust Rx coverage.

2014 is likely to be the beginning of an entirely new "medical culture" that the U.S. Rx industry will have to quickly learn how to manage in the years to come.

The new medical culture of 2014: "less is more"

So, for pharma execs across the U.S., 2014 will present the first manifestations of the broader Obamacare "medical culture" that will continue to take shape as the years go by. Generally, what can U.S. pharma expect? Reviewing all that we know today, and it is obviously a confused picture, it does appear that the new Obamacare Rx "ethic" will be built around the idea that, "less is more."

In general then, as this new medical culture begins to take hold, for the 85% of Americans who are currently enjoying some level of private medical care and who had access to the latest Rx prescriptions prior to launch of Obamacare, 2014 will likely begin to feel like they are getting "less" prescription drug care than they had in the past. However, for those 15% of Americans who for the first time will be getting access to many older, lower cost Rx products, it will definitely feel like "more" prescription care is being provided — a lot more.

For the U.S. pharma exec, then, there's more than a little bit to think about this year. My guess is that on several levels, 2014 is likely to be the beginning of an entirely new "medical culture" that the U.S. Rx industry will have to quickly learn how to manage in the years to come. There really is no other option.

About the Author

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US Pharma Challenges 2014

Federal policy makers continue to seek ways to prevent disease and improve care while reining in health care spending.

Pricing and personalized medicine are key themes shaping drug development and marketing in the U.S. in 2014, writes Jill Wechsler.

Amidst the turmoil over implementing Obamacare, federal policy makers continue to seek ways to prevent disease and improve care while reining in health care spending. Innovative therapies that keep patients out of hospitals promise to help realize these goals, provided industry, regulators and policymakers can address key scientific, regulatory and marketing questions in the coming months:

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Will health reform expand drug coverage?

The promise of Obamacare is that extending coverage to millions of uninsured Americans will greatly increase drug utilization and reimbursement. But the picture has been clouded by reports of new exchange plans

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with limited formularies and high co-pays for medicines, particularly for specialty drugs. Such actions threaten patient access to needed therapies, generating talk of legislation to curb specialty tiers and to extend Medicare Part D "protected drug classes" to private plans.

Are U.S. price controls inevitable?

Many analysts blame access problems on high drug prices, particularly compared to lower cost medicines in Europe and other regions. So far, pharma companies have deflected proposals to reduce public spending through rebates on drugs for low-income Medicare "dual eligibles" or by government negotiation of Medicare drug reimbursement. But limits on drug exclusivity have support, and specialty pharma will face more intense scrutiny this year.

Will inexpensive generic drugs continue to increase?

More than 80% of prescriptions in the U.S. involve generics, with the Medicare Part D program driving the trend. More will come to market faster with generic manufacturers now paying user fees to speed up the Food and Drug Administration approval process for these products. But the shift to generics may slow down, as many blockbuster drugs already have lost patent coverage.

When will biosimilars appear?

Insurers and pharmacy benefit managers are eager for less costly versions of key biotech therapies, but the first such product has yet to make it through the complex U.S. regulatory and legal framework. Many widely used biotech therapies will lose patent protection over the next few years, and dozens of small and large biopharma companies are lining up to develop comparable therapies. FDA promises further guidance on the testing needed to demonstrate biosimilarity, and agency officials will continue to meet with firms to help them establish viable product development strategies.

Many analysts blame access problems on high drug prices, particularly compared to lower cost medicines in Europe...

Is FDA blocking innovation?

FDA had approved only 26 new molecular entities as of early December 2013, much less than the near-record 39 new drugs in 2012. There's no slow-down in approvals, explained John Jenkins, director of FDA's Office of New Drugs, at the December FDA/CMS Summit; the problem is that fewer new drug applications were filed. Jenkins noted that a more transparent new drug review program is helping sponsors remedy shortcomings more quickly and rescue troubled applications.

Can personalized medicine fill pharma pipelines?

Access to genomic data and effective diagnostics will continue to spur development of therapies for small patient populations with serious conditions. Orphan drugs already account for a significant portion of new drugs approved by FDA, and that will increase as Big Pharma shows more interest in these markets. FDA will continue to encourage orphans and breakthroughs with special assistance to streamline development and approval.

What about treatments for major diseases?

At the same time, regulatory officials worry about declining investment in new therapies for broader conditions, such as diabetes and cardiovascular diseases affecting millions.

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Jenkins urged another look at "me-too" drugs. "Having more choice is good," he says, noting the first-in-class drug is not always the best.

Can new partnerships fill gaps in biomedical research funding?

The budget squeeze at FDA and the National Institutes of Health, along with declining drug company revenues, are spurring more collaboration across the biomedical research enterprise. Three leading cancer research centers recently formed a joint venture to investigate innovative pathways for developing cancer treatments. Major manufacturers are negotiating research agreements with biotech firms, instead of just buying them. Pre-competitive partnerships are proliferating, tackling data sharing and patent issues in the process.

Can clinical trials become more efficient?

High R&D costs underlie the hefty price tags on many new drugs, emphasizing the importance of streamlining research operations and testing requirements. Multiple partnerships and collaborative initiatives are working to establish standards, harmonize electronic data systems and utilize new models for protocol design. Yet concerns about patient privacy and safety complicate the process. Debate will continue over these issues, plus appropriate use of biomarkers and endpoints in clinical trials and the role of more innovative analytical methods and study designs.

Will drug shortages persist?

Patients and health providers become alarmed when they can't obtain needed medicines, and when alternate supplies from compounders turn out to be contaminated and lethal. FDA is moving quickly to establish policies and procedures authorized by new legislation to detect and prevent critical shortages and to regulate large-scale compounders of sterile injectibles. However, the long-term solution, say agency officials, is for manufacturers to invest more in systems to ensure consistent production of quality products, and FDA wants to see more action in this area.

How will social media transform pharma promotion?

Personalized medicine means more targeted marketing, along with less spending on traditional advertising. Reliance on legions of sales reps continues to decline as doctors and hospitals close their doors. Yet, FDA regulations limit marketer use of the Internet and electronic messaging systems to discuss their products. Pharma companies want to utilize social media to better educate patients about proper compliance and prescribing. FDA oversight of these strategies is critically needed.

Will FDA get sufficient resources?

Jenkins and FDA commissioner Margaret Hamburg also emphasized at the FDA/CMS summit the need for more resources to support the agency's ever-expanding responsibilities. While praising Congress for providing added authorities that will help FDA fulfill its mission, Hamburg urged the legislators to approve the "kind of real resources — not just new mandates and authorities"— needed to meet greater challenges. Jenkins expressed frustration that budget cuts and sequestration have siphoned off resources, including a portion of already-paid user fees. This development, together with the steady rise in fees supporting drug regulation, may prompt a broader re-examination of the user fee program in coming months.

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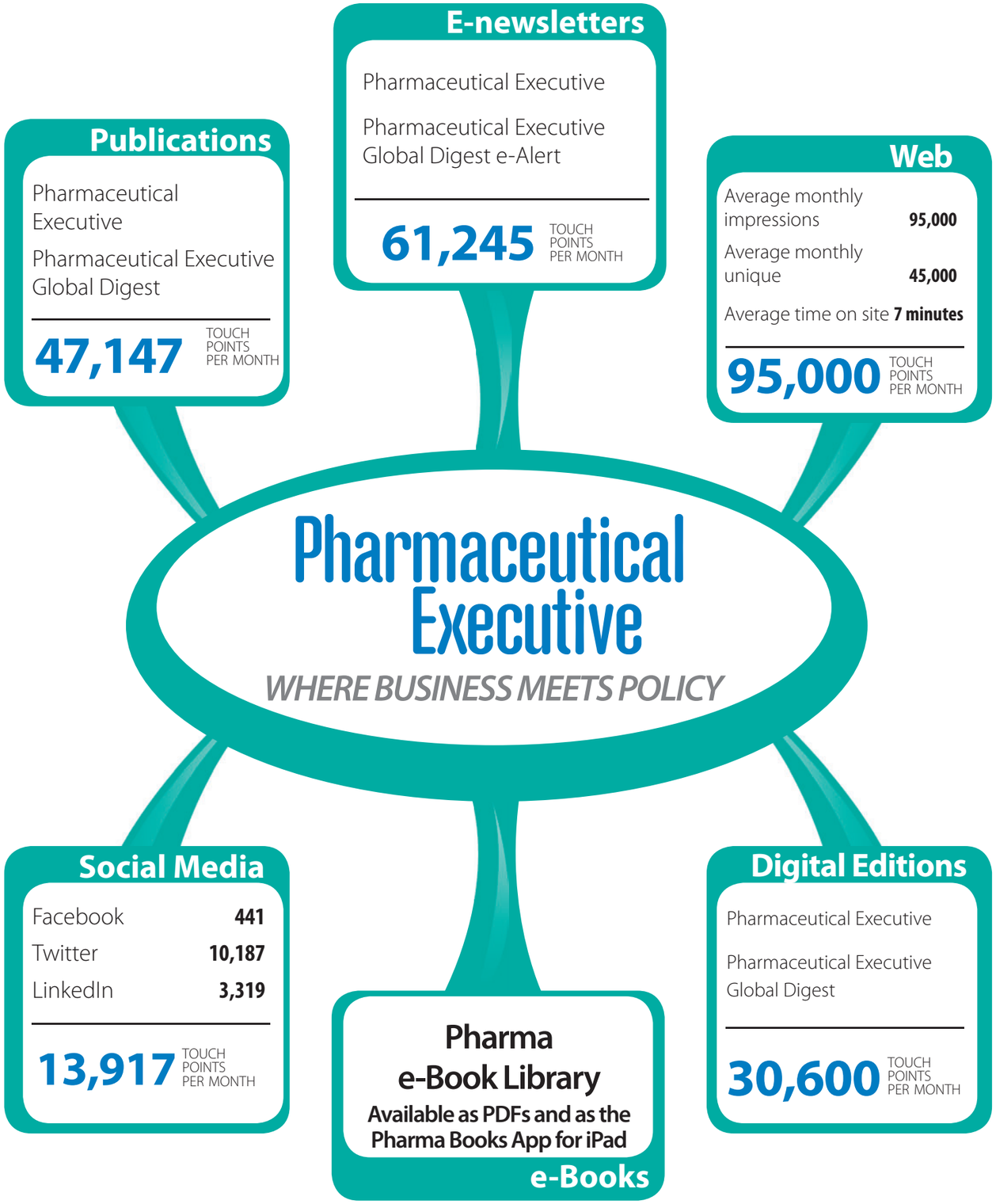

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2014 European Regulatory Outlook

Pharm Exec's EU correspondent, Reflector, looks at some of the European regulatory developments mooted for 2014 and anticipates their effect on the industry.

The European Parliament holds its elections in May, and many of the familiar faces that have supported — or attacked — the industry will disappear.

Personnel

Some of the big influences on the pharma industry in Europe next year — and for several years to come — will be the big changes upcoming in key personnel in the European Union institutions.

Vincenzo Lombardo/Gettyimages

The European Parliament will hold its five-yearly elections in May, and many of the familiar faces that have supported — or attacked — the industry will disappear. The composition of the next parliament will influence EU policy right across the board, from health to industrial affairs, and from intellectual property to competition. And the likelihood is that wide public disaffection with the EU will result in a parliament with a much more eurosceptic, radical, and unpredictable approach to policy-making — all the more disconcerting

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since this will be the first new parliamentary term since the parliament gained increased powers in EU decisions with the Lisbon treaty.

The European Commission's term also expires late in 2014, which means all the current 28 commissioners are out — and few, if any, of them will be back. Certainly there will be a new commission president — Barroso has said he is not bidding to return — and Joaquín Almunia, who has pursued the industry relentlessly on the patent pay-for-delay cases, will not retain the competition portfolio (although he may press all the harder for action on the outstanding cases as he clears his desk).

The legislative calendar

The EU will continue to grind through its legislative calendar in the field of health, notably on the below:

* New rules on clinical trials, in a belated bid to keep Europe an attractive location for clinical research after the debacle of the rules introduced in 2001, which made multi-center trials harder rather than easier to perform across Europe.

* The update to EU rules on medical devices (also covering in-vitro devices) proposed in 2012. The outcome, particularly in relation to diagnostics, will have more significance for personalized medicine than might at first appear.

* A proposal to charge fees to companies to pay for the new work on pharmacovigilance that the European Medicines Agency is increasingly undertaking.

* New rules adopted in November on countering serious cross border threats to health provided for joint procurement of medicines and vaccines. An agreement has been drafted and is scheduled for signature at the beginning of next year — which could challenge the ability of companies to negotiate individually with national authorities on procurement.

* Particularly on clinical trials and on medical devices, the race is on to secure full agreement of member states and European Parliament before the end of the parliamentary term in April 2014. Failure to agree by then could consign the proposals (and all the laborious work on them so far) to the legislative dustbin, requiring completely new proposals to be made by the next European Commission — sometime in 2015 at the earliest!

Strategic pressures

Strategic pressures — driven more by the political context than by specific policy-making — will exert increasing influence on the industry.

Strategic pressures — driven more by political context than policy-making — will exert increasing influence on the industry

* Austerity economics and demographics will focus thinking ever more closely on the new slogan of sustainable health systems (which can often be translated as cuts in current health spending).

* Greater attention to prevention will offer opportunities for vaccines, for diagnostics, and for screening. Greater focus on value-for-money — and more sophisticated evaluation mechanisms that recognise the concept — can offer opportunities for innovative medicines.

* Calls for more equitable access to healthcare, which form an important element in the 'sustainable health

systems' concept, could offer some opportunities for redressing the imbalances in availability of medicines across Europe – that is, if the momentum results in increased reimbursement in countries currently offering limited access (predominantly in eastern Europe).

Specific changes in administrative arrangements confronting will present challenges as well as opportunities.

* Implementation of the rules on rights for cross-border patients, which has just started (very slowly in most countries) could also bring opportunities, as, in addition to its specific provisions for cross-border prescribing, it could expose wide discrepancies in many aspects of healthcare provision.

* Widening demands for accountability, transparency and good governance in all aspects of business and politics will tighten monitoring on the drug industry and on regulators. Calls for stronger provisions to prevent conflict-of-interest will multiply in the face of persistent public distrust, and even the pro-active publication of clinical trial data foreseen by the European Medicines Agency for 2014 (and the European Parliament's requests for greater disclosure in the new clinical trials rules) is unlikely to satisfy the gathering chorus seeking more open access to information.

* Trade issues will preoccupy many managers with international responsibilities. The EU–US trade talks may deliver some of the hoped-for alignment of regulatory requirements during the course of the year. If India's patent law continues to prove permeable, circumvention rather than expiry will remain a challenge to patent-holders. And increased intervention in trade talks of supporters of more open access to medicines will further complicate many already-complex negotiations on agreements with implications for the industry.

Challenges and opportunities

Specific changes in the administrative arrangements confronting the industry will also present challenges as well as opportunities.

* There should be new opportunities for research funding from the EU's $100bn programme to support innovation which comes into effect at the start of 2014 and runs through to 2020. As much as a tenth of this funding could be accessible for life-sciences research. Much of the money will be channelled through IMI2, the successor public-private partnership to the Innovative Medicines Initiative, which also kicks off in 2014. Favoured areas will include chronic diseases such as diabetes and dementia, and attempts to fill the antibiotics gap.

* Within the European Medicines Agency, efforts will continue to derive greater efficiency from the almost constant reorganization underway since Guido Rasi took over two years ago. In theory, the closer interaction he has been seeking among the agency's various committees should provide a more coherent and streamlined approach to decision-making on everything from marketing authorizations to delivery of advice. But the strains as the workload grows are evident to everyone in contact with the agency,

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and tighter resources — the agency faces a budget cut in 2014 — are likely to make implementation even harder.

* In broader terms, the pressure will continue to grow for closer links between marketing authorization procedures and health technology assessment.

* New science and new technology will continue to open up new opportunities that will also present new challenges. Growing understanding of disease and of mechanisms of agents, together with the capacity for handling ever-larger masses of data, will support the development of more targeted therapies — but will at the same time demand radical shifts in the thinking on clinical trial design, in marketing authorization procedures, and in the broader evaluation of risk/benefit. Additional challenges — particular to Europe — will come from public demands for protection of personal data, which could seriously handicap the exploitation of large data sets necessary for real development of personalised or stratified medicine.

* As the EU's legislation on combating falsified medicines comes more fully into force, the industry will have to put in place measures for identifying and verifying individual packs — and 2014 is the year that major decisions will be required on methods and on investment. The opportunities for combating the relatively limited level of counterfeiting in Europe are at risk of being seriously outweighed by the costs of the new systems, whichever are chosen.

Regulatory Agencies Establish Three Big Goals

The growing emphasis on transparency is expected to intensify in 2014.

Regulators are pushing towards not only improving product safety but also ensuring greater clarity around information and harmonizing how that information gets collected and used, writes Erik Gaussens.

The past year has seen a growing emphasis on transparency, which is expected to intensify in 2014. In addition, agencies want to improve the submission process by the simplification and harmonization of procedures. The third big trend has been to increase collaboration between regulatory authorities around the world — in particular between the U.S. and the European Union (EU).

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Data under the spotlight: Europe's XEVMPD

One of the most significant moves towards enhancing transparency began in 2011 with the announcement that the European Medicines Agency (EMA) would require companies to begin submitting their product information —from basic

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facts such as name, date of approval, therapeutic area and dose to more-detailed information such as known adverse events. This was the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) initiative that became mandatory in July 2012.

For the XEVMPD to achieve the goal of data transparency and clear identification of a product, it was imperative that the data be updated, clean and reliable. However, when the Agency began reviewing the XEVMPD data, it became clear that the quality of data entered was poor, and as a result, the XEVMPD was put on hold for several months.

In November 2013, the Agency began issuing quality control notices and advised that it would provide new guidance in January 2014, after which marketing authorization holders can begin reviewing the data they had previously sent to the XEVMPD.

From June 2014 to the end of the year and in keeping with the Agency's new requirements, companies will be expected to update their records. Performing that update will significantly increase companies' workloads, not to mention the maintenance process that must follow on from the updating of XEVMPD records.

Agencies want to improve the submission process by the simplification and harmonization of procedure.

An era of openness

Access to information has been high on the minds of regulators in other respects. The US Food and Drug Administration (FDA), for example, launched its Transparency Initiative in June 2009, with the goal of promoting innovation and improving the regulatory process. In Europe, the European Commission has been seeking greater oversight and improved monitoring of drugs since late 2010, when it introduced a series of laws.

To meet those requirements, the EMA established the Pharmacovigilance Risk Assessment Committee (PRAC), which assesses all aspects of the risk management of medicines for human use. The schedule of PRAC meetings and the minutes of the meetings are made public through the agency's website.

Recognizing, however, that the public was by and large unlikely to visit the website, the Agency took a more direct approach in 2013 by introducing a list of medications that are subject to additional monitoring. Since October, for each product in question, companies have been required to place an inverted black triangle on a drug's package leaflet and on the summary of product characteristics, as well as a short description that explains what the black triangle means.

In a further move to enhance insight into drug safety, the Agency published three more modules of the good pharmacovigilance practices guidelines:

1. public participation in pharmacovigilance;

2. continuous pharmacovigilance, ongoing benefit-risk evaluation, regulatory action and planning of public communication; and

3. international co-operation.

The new modules serve to move pharmacovigilance from pure surveillance of a drug to continuous analysis and evaluation of safety information about the impact of each drug or active ingredient on exposed populations both in member states of the EU and in other countries.

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More controversially, the Agency announced that from January 2014, it will start publishing data submitted for regulatory review through the European Union Drug Regulating Authorities Clinical Trials (European Clinical Trials Database). Although the pharma industry has largely supported greater openness, this latest decision has raised alarm bells amid concerns over the privacy of clinical trial participants as well as over the protection of intellectual property.

The FDA announced in June 2013 that in an effort to improve the drug development process, it was seeking input with regard to making de-identified clinical data available; but the agency has to date not said it would publish data.

Harmonizing processes and procedures

Regulators are also striving to improve harmonization around pharmacovigilance. The EMA has increased consistency around pharmacovigilance case databases so that in the future, cases will be sent in electronic format and there will be no need for each country in Europe to have its own pharmacovigilance case databases.

> The third big trend has been to increase collaboration between regulatory authorities — in particular the U.S. and the EU.

Another area of harmonization involves

1. Periodic Safety Update Reports (PSURs), which are for products on the market.

2. Development Safety Update Reports (DSURs), required during clinical trials; and

3. The risk management plan (RMP).

Efforts are being made towards greater flexibility by permitting the use of individual sections that are common to more than one of the reports — despite the fact that those reports are prepared for different regulatory authorities and for different functions.

On one hand, by allowing the use of common sections, regulators hope to promote consistency and avoid unnecessary duplication while also improving efficiency for companies. On the other, the simplification does require companies to manage commonalities between the reports, coordinate bibliographic sections, and coordinate their signal management, risk-benefit assessment and PSURs, DSURs and RMPs.

Regulators are also eager to improve processes and procedures with regard to how submissions get made and how industry liaises with the authorities whenever possible.

Until recently, marketing application holders were able to use the Agency portal for submissions made through the Centralised Procedure but had to ship CDs or DVDs when submitting through the National Procedure, the Mutual Recognition Procedure (MRP), or the Decentralised Procedure (DCP). In mid-2013, the Agency made available the Common European Submissions Platform (CESP) for submitting regulated documents.

CESP is now largely accepted by most European regulators for all procedures except those sent through the Centralised Procedure, which has its own specific EMA portal. The streamlining of the submission process is expected to (1) shorten the time from submission to acknowledgment of receipt by regulators and (2) result in a logistical saving for companies because companies won't be required to burn and ship CDs in future.

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With regard to submissions made through the MRP or DCP, the EU is working towards what it calls a comprehensive model to replace the parallel nation model, whereby independent electronic Common Technical Document (eCTD) sequences are submitted to each country. The change follows the decision to require companies that submit through the DCP to use the eCTD format from early 2015.

Global interaction

The past year has also seen increased collaboration between global regulatory authorities — particularly the United States and the EU. For example, the FDA and EMA have been allowing cross-access to pharmacovigilance databases, and the two meet regularly to compare their findings about the same products. In 2013 the agencies reinforced their collaboration, which means that in the future, companies filing a PSUR in one region would be taking a risk if they failed to disclose information from the other region.

Greater clarity around product data would be not only to the benefit of the authorities but also to pharma companies and the patients they seek to serve.

The two agencies are also working towards greater collaboration on certain quality and sections of chemistry, manufacturing and controls that are relevant to Quality by Design, which ultimately could ease batch delivery and minimise inspections for companies that adhere to the QbD processes.

And in the second half of 2013, Japan's regulatory authorities — the Japanese Ministry of Health, Labour and Welfare; and the Pharmaceuticals and Medical Devices Agency —began to enter information on good-manufacturing-practice (GMP) compliance as it relates to Japanese manufacturer, in the EudraGMDP (European Union Drug Regulating Authorities good-manufacturing-and-distribution-practice database), which the EMA operates to support the exchange of information on GMP compliance.

Conclusion

As regulators continue promoting greater transparency and greater harmonization across pharmacovigilance, regulatory submissions and manufacturing, companies will have to find their own ways to respond and adapt. Greater clarity around product data would be not only to the benefit of the authorities but also to pharmaceutical companies and — most important — the patients they seek to serve.

About the Author

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The Regulated Cloud

Using the regulated cloud is a fully compliant, highly secure and very advantageous approach… and the way of the future.

Rik Van Mol explains why cloud computing is the key to the future of content management in life sciences.

Much of a life sciences company's most precious intellectual property falls into the category of regulated content, ie, content that must be created, approved, tracked, stored and updated in accordance with specific government regulations. For the past two decades, companies have managed their regulated content by maintaining elaborate content management systems within their firewalls.

Today, however, given fundamental changes in the healthcare landscape and companies' business models, these solutions are obsolete, inefficient and, in many cases, ineffective. The best practice in managing regulated content is to deploy solutions in the regulated cloud — an environment that conforms to the strict technical and quality standards established by global health authorities. Manufacturers may at first be hesitant to send proprietary intellectual property and regulated content off to the cloud and to use software that a vendor manages across multiple tenants. Using the

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regulated cloud is, however, a fully compliant, highly secure, and very advantageous approach … and the way of the future.

A Demanding Industry

Perhaps no industry is as heavily regulated as life sciences, since laws dictate not only how various clinical and operational processes are performed, but also how they are documented and even how that documentation is handled electronically. Regulated content includes clinical trial protocols, safety reports, health authority submissions, manufacturing processes, formulations and promotional materials. Non-compliance with regulations such as 21 CFR Part 11 and EU GMP Annex 11 that govern the creation, storage and use of such documents can cause safety issues and result in criminal liability as well as civil and regulatory authority penalties or fines.

For years, life sciences companies have managed their regulated content using software designed for general, industry-wide platforms that is then modified for specific uses. These general-purpose tools, especially once customized, are complex systems to deploy, master and maintain. Consequently, they are no longer suited to the industry's current environment and business requirements.

A Changing Climate

As it relates to regulated content, the life sciences industry has changed significantly since content management software was first introduced:

• ***Companies are no longer autonomous.*** While life sciences companies once performed nearly all of their business functions internally, they now rely on a mix of external partners from CROs to co-marketers. They need to be able to exchange content and collaborate with their external partners, while maintaining system security, regulatory compliance and the integrity of their information. Any shared content management system must maintain tight security and at the same time allow users to be added quickly, provide easy role-based access to content and be intuitive to use.

• ***Companies operate globally.*** To remain competitive and to serve a global marketplace, life sciences companies are doing business with partners and affiliates around the globe. Their technology platforms and software solutions must therefore be flexible and affordable enough to serve even the smallest, most remote partners and affiliates. All users need the same easy access, speed and performance from the software that central offices enjoy, and the consistency of content must be maintained across borders.

• ***Regulatory demands are growing.*** Regulatory restrictions and the pace of regulatory change are intensifying. In general, regulatory bodies have placed more and wider restrictions on the storage, distribution and tracking of content, as well as the validation of storage systems. Thus, any system for managing regulated content must accommodate constantly changing regulations, and system changes must be readily validated as compliant.

• ***The budget is constrained.*** Declining revenues have forced companies to reduce costs — including those associated with mission-critical systems. Companies, therefore, need a more cost-effective alternative to implementing and maintaining the complex customized solutions of the past, the cost of which can run into millions of pounds per year.

Antiquated Solutions

Traditional content management software solutions are ill-suited to these new working conditions and no longer deliver what companies need, particularly

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when it comes to collaboration. Companies that maintain their regulated content within their firewalls have three options for sharing it with partners:

1. They can grant partners access to their internal systems through virtual private networks (VPNs) or by issuing company laptops, with all of the logistical complications that entails. This process can easily take up to three months to complete.

2. They can implement a second level of technology to share content externally. This model quickly degrades into an environment with uncontrolled sharing, version confusion and an inability to maintain a single master file that reflects the authoritative version of the truth.

3. They can take the path of least resistance and simply e-mail documents to partners or use an electronic drop box. Inevitably, this leads to the same uncontrolled environment described above.

Existing systems are painfully difficult and expensive to deploy, update, maintain and support. Often, the hassles and expense involved mean that affiliates do not get the same functionality as headquarters, that smaller companies must manage their regulated content manually, and that companies fall behind in their upgrades.

Failing to upgrade the software regularly can impact user acceptance, as performance and functionality are stagnant in the face of changing needs.

Making even simple changes (such as adding new fields or document types) involves many elaborate steps in system validation, installation and deployment, requiring considerable IT resources.

Technology to the Rescue

Fortunately, all of these challenges can be met by adopting new technologies.

The first advance that can be brought to bear on managing regulated content is a very

simple, intuitive user interface. Consumers using software on the Web, such as Facebook, Amazon and Google, can use these tools instantly, with no training, because the navigation and functionality is obvious. This same type of easy, user-friendly experience is now available to business users working with their regulated content management systems.

The second is cloud technology. Cloud computing is an architectural model through which a vendor provides software to multiple subscribers, or tenants, from a single, shared instance of the application which is maintained centrally. (Common consumers examples are Spotify and Apple's iCloud and business examples include LinkedIn and Salesforce.) Users can access the software with an Internet connection and need no special hardware. Customers maintain full custody of their content, which is separated from others' by impenetrable partitions.

This turnkey arrangement delivers a number of benefits over single-tenant instances of software that apply directly to the challenges of managing regulated content today:

• ***Speed and adaptability.*** Administrators can configure and update an application using simple point-and-click tools. Thus, a change that takes months to develop and deploy with a hosted/on-premise environment takes just a few minutes. New users, both internal and external, can be added just as easily.

• ***System performance and quality.*** The provider offers technology that would not be feasible for any one customer and can maintain a continuous stream of innovation. The provider handles all system upgrades centrally, so all users are always working on the latest release. Additionally, the system can continue to sustain peak performance, even as usage increases.

• ***Cost savings.*** The solution is hosted by the vendor who can achieve economies of scale and spread costs across multiple companies, so subscribers need not invest in any equipment or data centre space. Companies pay only for the capacity and storage that they use. This makes content management affordable to even the smallest organisations or business units.

• ***Flexibility and scalability.*** The system's capacity is elastic, so the vendor can adjust capacity for any subscriber as business parameters change.

It is important to make the distinction between true, multitenant software implementations and software programs that are simply hosted off premises by vendors. The latter are still single-tenant solutions, meaning that each customer has its own dedicated server running its own version of the application, which the vendor configures and maintains for the client. Each time there is a change, the application must be redeployed for each customer — an expensive process with no economies of scale. Plus, the arrangement is subject to annual maintenance and support fees. It is the multitenancy aspect of an application, not strictly the off-premise hosting, that delivers the benefits of the cloud.

The Regulated Cloud

When cloud computing is used for managing regulated content, the solution must go beyond what is required of non-regulated business applications. Given the security issues and validation requirements involved, the regulated cloud must offer:

• An environment that is both validated and auditable. For other applications, users do not need to know exactly where their information is stored within the cloud. Regulated content, however, should be stored in a fixed location that can be visited, audited and validated to the company's

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satisfaction. All software releases must be validated by a trusted system validation service.

• Adherence to Standard Operating Procedures for quality software development and system maintenance.

• A world-class security infrastructure. Multiple layers of firewalls ensure high levels of protection against intrusion, and security measures identify and close vulnerabilities.

• Robust and flexible security at the content level. Security policies must be user-based, and advanced controls are needed to enable user authentication, log user activity and define user profiles by document stage.

• Business continuity and disaster recover measures that match, if not exceed, what companies would maintain on their own.

• Data segregation for content files, metadata, full-text search indexes and application configurations. The exact location of each should be clear.

Ron Calderone, executive director of Information Services and Management at Unigene Laboratories, maintains, "A system in the cloud is as secure as its host." When security measures include nightly backups, inherent redundancy, regular external security audits and a tested business continuity plan, he advises, "… the cloud can be a highly secure computing environment."

Beyond these basic protections, the ideal software solution can support global collaboration, compliance with changing regulations and more cost effective operations.

Users anywhere in the world can log into the secure environment using any device with an internet connection, a web browser, and a username and password, and then begin work with little or no training.

Content is visible to all authorized team members (internally and externally) immediately, and documents stay in a controlled environment throughout the collaboration process.

The logic behind document lifecycles, workflows, properties and actions is easily configured, yet strictly controlled. Updates are made within the underlying application by the vendor and are pre-validated before being released simultaneously to all subscribers. New functionality is turned off by default and must be activated by the business administrators.

By combining a user interface that is intuitive with a world-class infrastructure that is rigorously protected, cloud-based platforms offer companies the best of all worlds for managing their regulated content.

Systems maintained in the regulated cloud are accessible to partners and affiliates globally, supporting collaboration between internal and external partners. Yet content remains in a secure, controlled, audited environment.

The best solutions mimic the usability of popular, consumer software on the web — even while providing all the powerful features that users need for peak efficiency.

The multitenancy structure also means that upgrades are deployed automatically. Users are always on the most current release, business systems are validated and business practices remain current with legislation. The cloud platform also spreads costs across multiple clients and permitting companies to pay only for the capacity they need.

About the Author

Rik Van Mol is Vice President Veeva Vault, Europe, Veeva Systems. Rik has over 15 years of business/IT consulting and regulated content management experience in life sciences.

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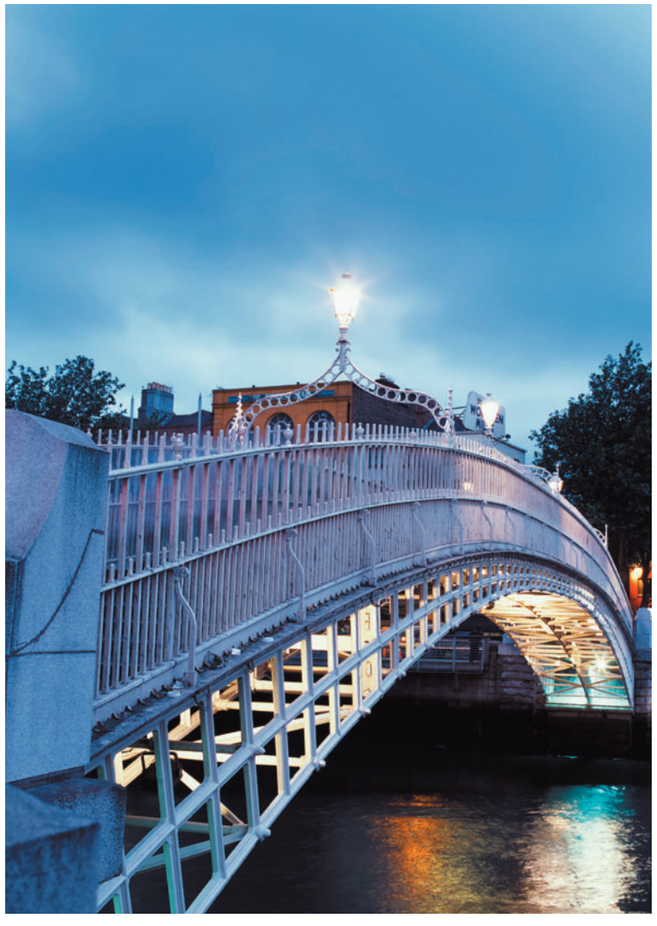

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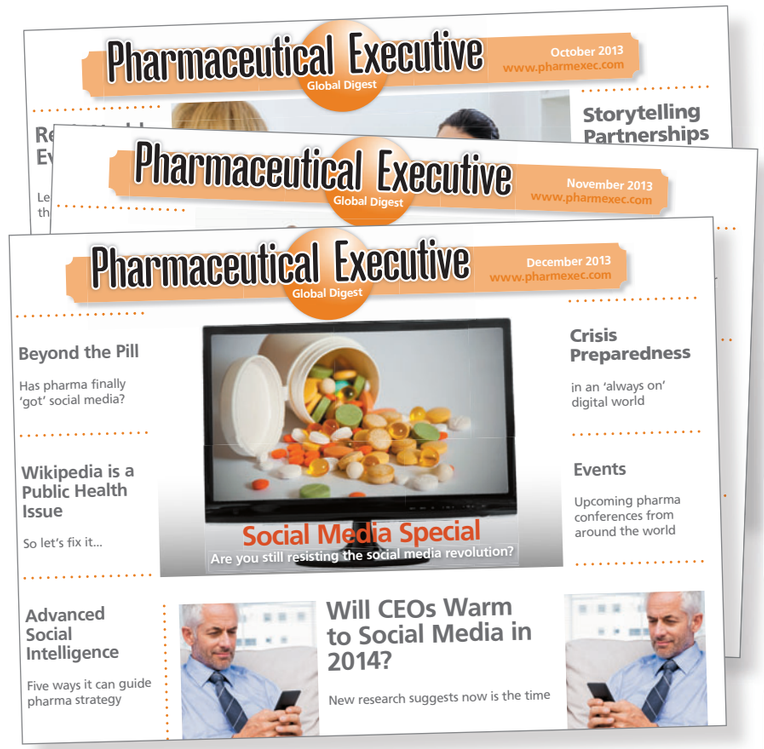

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