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Interview

Hospira's Paul Greenland talks about the launch of the first mAb biosimilar and the new challenges in development.

Financing

European biotech companies have added crowdinvesting to the financing toolbox

Nagoya Protocol

Poor implementation of benefit sharing could block biotech innovation in Europe

Antibiotics

New EU financing instrument to close funding gap in high-risk antibiotic development

EuroBioFairsCompass

The unique guide to the top life sciences events in the second half of 2015

Tracking stealthy killers

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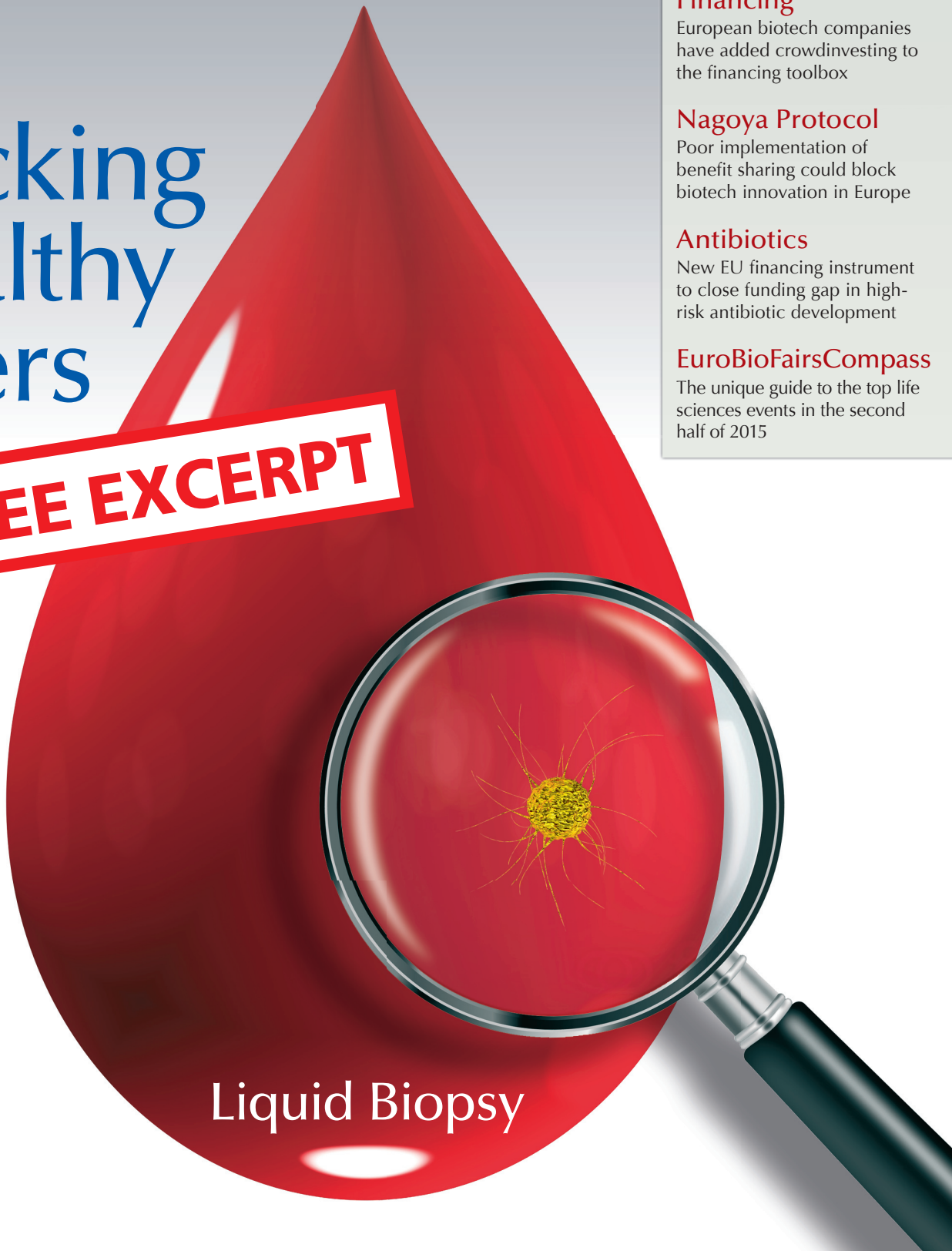

Liquid Biopsy

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COVER STORY

Fishing malignancy from the stream

For over a century, oncologists have struggled to understand how cancer develops resistance to treatments. Now novel ultrasensitive techniques that allow them to track cancer mutations and circulating tumour cells in the bloodstream are raising hopes that testing could soon detect initial signs of tumour resistance and response to treatment, as well as reliably predict therapy outcomes. Though it's early days yet, Life Sciences and Big Pharma firms are partnering to validate liquid biopsy methods in clinical trials.

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FINANCE

Fundraising with schools, not sharks

In the past several months, Life Sciences companies all over Europe have successfully capitalised on crowdinvesting schemes. EuroBiotech introduces the most relevant campaigns and summarises the prevailing business models of high-flying platforms.

BIODIVERSITY

Balancing out the Nagoya Protocol

The EU's regulation for the implementation of the Nagoya Protocol is seeking to establish a clear access and benefit-sharing regime, but scientists and industry leaders are highly concerned about certainty and clarity.

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EDITORIAL

The challenges

Innovation has always challenged society and law – and vice versa. The latest and most ambiguous case has been the intervention in human germ lines with genome editing. In May, EU and US policymakers underscored the importance of upholding the current ban (see p. 3) after Chinese researchers revealed failed testing in the area on non-viable embryos. But what if it had worked? Is a ban acceptable if you could save an embryo with a lethal gene defect? Other modern quandaries are being posed by biotech breeds derived from techniques so new that they're not covered by current EU law (p. 10).

Limits are easier to set in emerging fields like liquid biopsy, where blood could soon tell us which cancer therapies are most appropriate (see p. 14). EuroBiotech asked industry leaders about the best ways to validate the approach. They told us implementation was key – just like their counterparts in the area of biodiversity legislation, where the Nagoya Protocol is set to take effect (p. 52).

Fortunately, there are plenty of areas where society can still count on returns from innovation, and innovators on plenty of reinvestment (p. 12, 36).

Making innovation perceptible to society is crucial to maintaining a viable life sciences sector in Europe. And only that acceptance will help us strike the right balance between regulation and scientific freedom.

Thomas Gabrielczyk
Editor-in-Chief

FREE EXCERPT

No-GMO wave

AGRIBIOTECH In 2012, the EU's "New Techniques Working Group" (NTWG) submitted its final report on novel biotech methods for genetic manipulation of crops to the European Commission. Its report investigated if crops designed by novel tools such as genome editing or gene silencing, are GMOs that must be approved and safety assesed under EU law. However, until now, the Commission had not made a political decision on the matter. The US company Cibus has now created precedents. In Germany it has already received deregulated status for its herbicide-tolerant "SU canola" from the federal authority BVL. This means, that Cibus can immediately plant and market its crop without any need to label it as a GMO. The company has also filed for deregulated state in Spain, Sweden, Finland, Ireland and the UK in order to safe up to US$15m for an EU GMO approval. In March, the German Agriculture Ministry rejected objections by anti-GMO campaigners from Testbiotech who claimed Cibus method was GM. If other regulators follow the German example, a wave of genetically engineered "no-GMOs" are set to enter the bloc.

Using natural gene repair

Cibus' canola has been genetically engineered by targeted mutagenesis. Its does not contain any foreign DNA sequence such as GMOs. In contrast, the company uses so-called gene repair oligonucleotides (GRON) to inactivate the crop's acetolactat synthase (ALS) gene: in a first step a GRON pairs with a complimentary target sequence in the ALS gene. However, as the GRON differs only in one or two nucleotides, mismatches in the crop's DNA occur that are corrected by gene repair enzymes. Afterwards, the GRONs are completely digested and the ALS gene then contains an inactivating mismatch mutation. As the GRON is transient and the product is indistinguishable from conventionally mutated crops, the BVL and NTWG say it is not a GMO. The same applies to genome edited crops. ■

Heard in Brussels

Nagoya – protecting resources with paperwork

BRUSSELS *European Biotechnology Network had the good fortune to moderate the 8th Berlin Conference on IP in Life Science, which this year had a focus on natural products. "That will be interesting," I thought to myself, thinking about the world of complex structures and challenging development pathways. "Interesting" soon paled into insignificance as I fell headlong into the tiger trap that is the Nagoya Protocol, coming soon folks to a country near you.*

CLAIRE SKENTELBERY
Secretary General of the European Biotechnology Network

For those of you uninitiated in such matters, the Nagoya Protocol is a global programme with the extremely relevant intention to regulate access to genetic resources and ensure the sharing of benefits arising from their utilisation. Europe, as we recall, knows a thing or two about 'accessing' resources from countries beyond its immediate vicinity without the express written consent of their owners and Nagoya is a worthy platform to prevent sticky-fingered organisations from literally vacuuming up local resources and knowhow without a) the locals' consent and b) full engagement financially and culturally.

This all sounds great and, as usual, the liberation of keen regulators around the world has ensured that it is now massively complicated and is already protecting local resources by ensuring that nobody can be bothered to fill in all the forms to pick a plant or sample the water (see p. 52). This learned column however wants to focus on what happens when Nagoya arrives in Europe, which it will do in October and has to be implemented.

And when I say implemented, I mean into all legal systems, and Europe has many more of those than a simple headcount of countries. Spain is my favourite example, where Nagoya will be implemented by each of the 17 autonomous communities. So, sampling natural resources in Spain (including those found in marine ecosystems) could involve discussions with ALL the regions in which your bacteria, nematode or plant can be cultivated, and that is a lot of paperwork in a wide variety of dialects.

Europe is woefully underprepared for the level of stringency required by Nagoya, most countries aren't ready for October because they didn't pay attention when they should have, which will result in the usual amusing quagmire that Europe is good at creating. If this sounds flippant, perhaps it is, but this column comes in the light of the fact that research into, and commercialisation of natural products has collapsed in the years that have seen increasing regulation on access, with, I recall, a reduction of the big companies active in natural products declining from 13 to 3 (don't quote me on that exact number but it is close).

The irony is that you only have to step outside your back door to find sufficient genetic resources to last a lifetime of natural product research. You don't have to go to anywhere exotic (and fill in lots of forms) and European implementation of Nagoya will probably ensure that we all look closer to home in the future. ■

Picture: EBN

With the Cluster-Chip, researchers were able to detect tumour-cell clusters in the blood of 30% of the breast cancer patients they tested. Monitoring these potentially metastasis-inducing cells can help improve diagnosis.

FREE EXCERPT

Needles in haystacks

LIQUID BIOPSY Detection of minimal residual disease in cancer patients who have undergone surgery and first-line therapy has become the next big goal for oncologists. Until now, it's been impossible to detect the few tumour cells in the blood that manage to escape treatment and eventually lay the foundation for deadly metastases, therapy resistance and relapse. However, recent advances in the area of liquid biopsy suggest that new analytical tools able to identify circulating tumour cells may soon open the door to serial blood analyses to guide personalised treatments and predict therapy outcomes.

Everything seemed to be back on the right track for Sophie following several cycles of chemo- and targeted therapy. "Her tumour shrank like ice in the sun. It completely disappeared," says her mother. What the schoolgirl's doctors couldn't see was that a few tumour cells that didn't respond to treatment had broken away from her primary tumour and entered her bloodstream. Nine months after her initial treatment, a relapse killed her.

Globally, more than 95% of all cancer deaths occur after relapse. And circulating metastasis initiator cells (MICs) – which enter distant organs from the bloodstream and form new tumours – cause them. Cancer specialists therefore view identification and destruction of MICs in the bloodstream as an essential step towards getting on top of the disease. The problem is that we still don't know enough about the molecular characteristics of those cells, or how they evolve.

Technological advances over the past two decades are starting to change that by paving the way for liquid biopsy – the systematic detection and analysis of circulating tumour cells (CTCs), needles in a haystack made up of billions of normal blood cells. Among researchers and life sciences companies, excitement is growing as evidence mounts that a simple blood draw is now able to reveal whether a therapy has actually worked or not. The potential impact for patients is high. If CTCs, circulating tumour DNA (ctDNA) or vesicle-coated mRNA and – most exploratory – micro RNAs (miRNAs) can be used to detect minimal residual disease (MRD) and predict the probability for distant metastases, it would accomplish a task that neither radiological disease monitoring nor analysis of tissue biopsies has been able to solve so far. Recent research results suggest that liquid biopsy can detect development of resistant tumour cells up to ten months earlier than radiological methods can. Evidence that high numbers of CTCs in the blood correlate with a bad prognosis is documented for breast cancer, metastatic relapse and progression in prostate, lung, and colorectal cancer. That's why liquid biopsy as a method for tracking the molecular evolution of tumours has begun to draw major attention in pharma companies.

THOMAS SCHLANGE
Bayer HealthCare, Wuppertal

? What do liquid biopsy methods promise?

! *Finding biomarkers through a simple blood sample that shows us if a cancer therapy actually works would improve the situation for both patients and drug developers. It would allow us to follow the disease and adapt therapy individually over time. Today, we have one CTC-based prognostic tumour test. In the future, we aim to have predictive tests.*

Trying to make biopsies a thing of the past

"The problem with solid tumours is that biopsies don't allow us to track changes in the tumour's molecular properties, such as mutations that lead to therapy-resistant cell clones," says Thomas Schlange, Global Biomarker Research at Bayer HealthCare in Wuppertal. "Biopsies are often difficult to obtain, and they are also burdensome for the patient. They thus can't be taken serially to check response to targeted therapies. Liquid biopsy provides the opportunity to see a given tumour's full molecular heterogeneity, and to follow its changes over time," he adds.

Although most technologies aimed at isolating CTCs and profiling their mutations, gene and protein expression have been in development for less than 20 years, and have only been validated in small clinical trials, interest in the area is high. More and more companies are edging into the liquid biopsy market, including pharma heavyweights like J&J, Lilly,

» Read the full story in the printed issue.

Picture: MGH, Georgia Tech (left), Bayer Healthcare (right)

FREE EXCERPT

Fighting for access

BIOSIMILARS The first monoclonal antibody biosimilar reached the European market this year, and Hospira was in on the action. Over the last seven years, the company had already launched two copycat versions of biologics. Paul Greenland, VP of the biologics division at Hospira, talks about what it takes to launch a biosimilar on the European market.

EuroBiotech_It was just a matter of hours after J&J's Remicade (infliximab) patent expired before the first biosimilars, among them Hospira's Inflectra, hit the European markets. How was the launch for you?
Greenland_*It has been a fantastic few weeks, or months rather, for Hospira. When the biosimilar was approved by the EC back in September 2013, we were only able to launch on some of the smaller markets due to patent restrictions. So the real excitement came in February this year, when the patents lifted in most of the major European markets. It has been a very busy few weeks.*

EuroBiotech_The biosimilar market must be quite profitable!
Greenland_*It's certainly a very attractive market. The size of the Remicade market before the biosimilars came was over €2bn. So the market is big enough for several infliximab biosimilars: Celltrion markets Remsima while we have launched Inflectra in all European markets.*

EuroBiotech_Small-molecule generics can take up to 90% of a market within months of a launch. What is the situation like for biosimilars?
Greenland_*The uptake for biosimilars is different from the uptake you would expect for generics. It's a much slower, steadier uptake. From our experience with biosimilars, we know that the uptake can differ considerably. For example, our EPO biosimilar achieved 40% market share, while our G-CSF biosimilar is at more than 70 percent market penetration. But that does not happen overnight or nearly as dramatically as it would do with a generic. This is mainly because there is no general agreement across Europe on pharmacy level substitution. In most countries in Europe, pharmacy-level substitution is discouraged for all biologics products, not only biosimilars. Therefore, the uptake is really dependent on initially getting clinician agreement that they want to use a biosimilar. And obviously, that takes some time.*

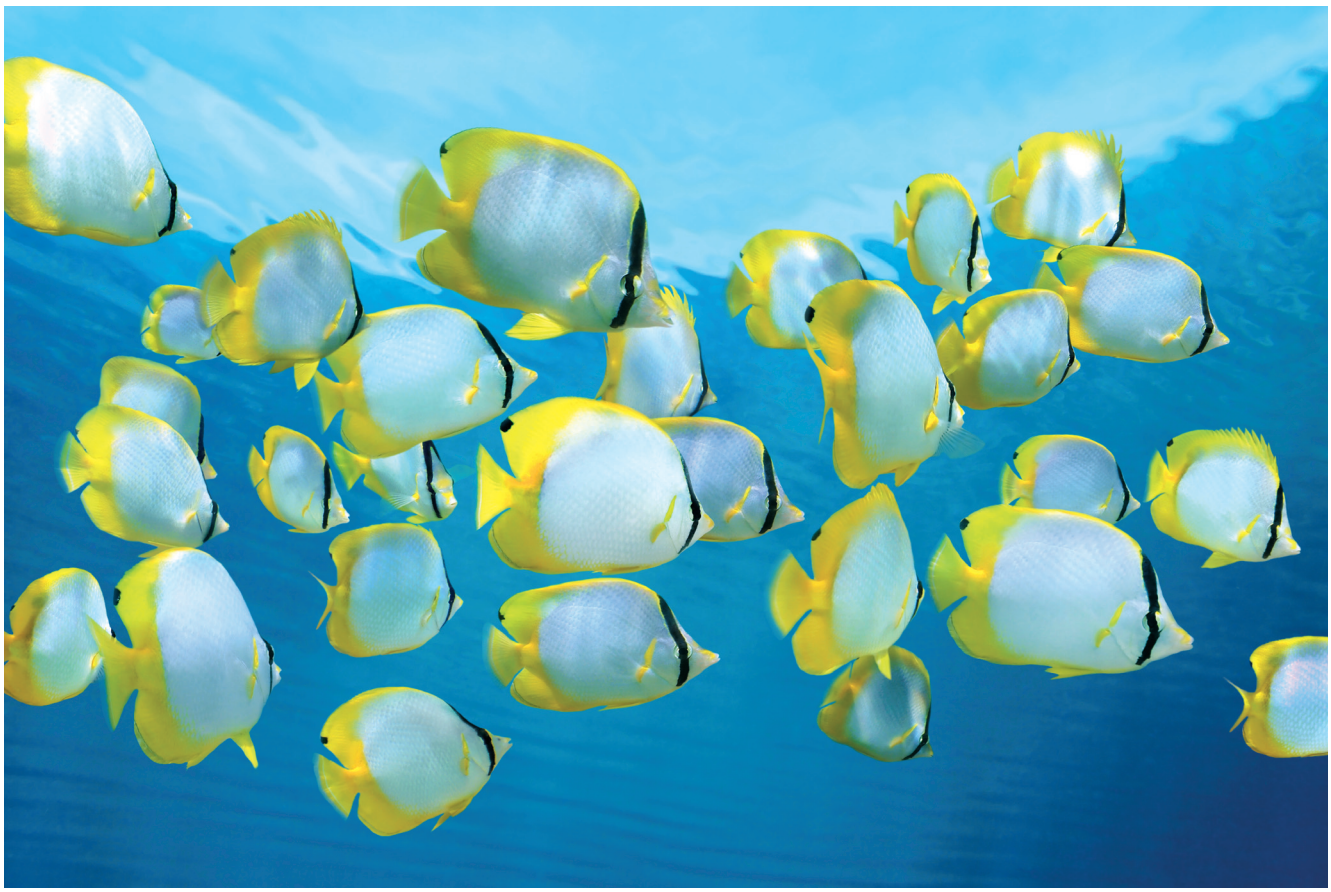
PAUL GREENLAND is Vice President Biologics at Hospira UK. He has been responsible for the launch of Hospira's three European biosimilar products Retacrit (epoetin zeta), Nivestim (filgrastim) and Inflectra (infliximab). Greenland is an active member of the European Biosimilars Group (EBG) and chairs their Biosimilars Market Access Group (EBG-MAG).

EuroBiotech_How will the infliximab biosimilar fare in comparison to the EPO and G-CSF biosimilars?
Greenland_*I think infliximab will lie somewhere in between the two. Exactly where, well, that is difficult to say. We are obviously hoping that it will be closer to 70%, and all our efforts are to try and make sure the uptake is as fast as possible.*

EuroBiotech_Reportedly, there is some skepticism prevalent among healthcare workers where biosimilars are concerned. Why do you think that is?
Greenland_*There is certainly a lack of understanding as to what biosimilars are. A biosimilar is only a biosimilar because it has gone through a certain regulatory pathway. The product itself is actually a biologic, just like other biologics. It is manufactured in exactly the same way as the originator biologic. It's approved for use like any other biologic, and it controls for quality like any other biologic. Sometimes people assume that biosimilars are actually different types of molecules to the originators. But they are not! They are just being approved slightly differently. We have also seen that in actual fact, there is a lack of understanding on biologics in general among physicians: […]*

» **Read the full interview in the printed issue.**

Pictures: Hospira UK



Democracy at work in biotech financing

CROWDINVESTING The past six months saw many European life sciences companies successfully cashing in substantial amounts to bring their businesses forward. In comparison, the almost €1m (£0.7m) for British Cell Therapy, exactly €1m for German Riboxx and €1.07m for French Eyebrain look meagre at best. Under close scrutiny, however, they could point to a revolution in the making: the money has been raised via crowdinvesting, a new funding source that is rapidly gaining traction in Europe's notoriously under-financed biotech world.

» Read the full story in the printed issue.

FREE EXCERPT

Lost in translation

BIODIVERSITY Last October, the Nagoya Protocol entered into force for all signing parties as an international agreement aimed at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way. As a signing partner, the EU has now passed a regulation that will enter into full force in October. Some European scientists and industry leaders have raised concerns that the regulation is too vague, and say that – at least initially – it will only breed confusion. Despite the challenges, many companies are already trying to develop best practices that stick to the letter and spirit of the agreement.

» Read the full story in the printed issue.

Picture: silencefoto/fotolia.com

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