TCG

WHITE PAPER

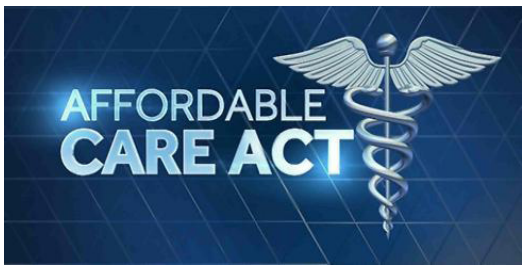
© fotomek – Fotolia.com

Healthcare Business Trends to Observe in 2014 / 2015

Business Trends to Observe in 2014

TCG is pleased to be connected to a worldwide network of experts in the Life Sciences and Healthcare Industry. Together with these experts, TCG offers its predictions of key business developments in 2014 and beyond. We present them briefly here for your review, but please contact us if you wish to discuss any points in greater detail.

Affordable Care Act will pressure US hospitals to change spending patterns

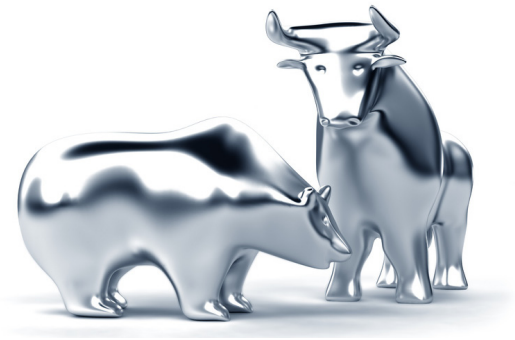


The implementation of the Affordable Care Act ("Obamacare") will intensify in 2014 and will continue to create pressure on hospital system finances. Many US hospitals have reduced staff and are cutting back any expenses that are not vital for their ongoing services. This is an important issue for all medical products companies but particularly for companies selling items considered less than critical. At the same time, the growing importance and long term benefits of better IT systems and methods to improve patient outcomes are getting more attention from hospitals' senior management. Companies who are considering launching a new product into the US hospital market need to plan for these changes, preferably early in the product development process.

New EU legislation on medical devices is on the way

In October 2013, the EU Parliament approved new EU rules on medical devices, driven by a 2011 scandal related to substandard breast implants affecting hundreds of thousands of women worldwide. The EU plans include tighter monitoring of device manufacturers – including unannounced inspections – but don't require a centralized EU pre-marketing approval process similar to that of the US FDA. Because of EU parliamentary elections in May 2014 and a subsequent change of Commissioners, any legislation must be finalized by March 2014 or might not be ready for implementation before 2015. Medical device companies– including US companies –who received a CE mark for an innovative technology, will still find the EU a good place to start generating early sales and cash flow. For global Business Development Departments, that means a stronger focus on Europe or collaboration with external partners that can provide support on both sides of the Atlantic.

Improved global financial markets will help US and EU companies expand



© tom – Fotolia.com

Many companies need to fill their product pipelines through faster internal development, external acquisitions or new overseas expansion. The easing of the public markets on Wall Street and elsewhere should help companies obtain the financial resources to accelerate internal development projects and to acquire new products or new businesses. But many smaller companies wont have the internal resources to manage this growth or to manage the process of finding and acquiring outside assets. These companies will increasingly turn to interim managers, or acquisition advisors to help them capture these growth opportunities.

Increased regulatory oversight of software

As software is a major part of more and more medical devices, the FDA has increased its reviews of software. In 2013, approximately 24% of all FDA warning letters were the result of software problems. The increasing numbers of new "Apps", including standalone software as well as those that integrate with medical devices have to be developed and tested according to FDA guidelines before submission. Companies interested in selling such products in the US market will be delyed unless they involve experienced regulatory and market experts long before they finalize product specifications. You will no longer be able to consider software as an "add on" item.

New German Government strengthens Innovations

Three months after the September 2013 elections, the new German government took over. The new Secreatary of Health, Hermann Gröhe will be focusing on new legislation for medical care, because the need for inpatient, outpatient and home care is predicted to double within the next 10–20 years. Of interest to many medical products companies, the new German Government also announced an „Innovation Fond", an initiative to accelerate the clinical use of new technologies. At the moment, this is only an announcement, and details will soon be emerging.

Hermann Gröhe,
Secretary of Health

Purchasing department becomes more powerful

For decades, purchasing decisions in hospitals were mainly driven by the personal preferences of physicians. One of the consequences of the Affordable Care Act is a greater focus on outcomes and reimbursement. This is especially true in the orthopedic segment, where the prices for similar products differ within a wide range. As a result, we will see ongoing consolidation of purchases by hospitals with the GPOs taking over a larger portion of supply budgets. To maintain or grow product sales, companies should leverage their options through direct links to the purchasing managers as well the physicians.

Lack of VC capital slows down innovative products; new financial approaches are emerging

© Maksim Kabakou – Fotolia.com

The global lack of "at risk" venture capital is causing a growing number of smaller companies, many with valuable technologies, to slow down their development of new products. These innovative VC-backed companies have traditionally been the source of new technology for larger companies, who still have the need for new products to address pipeline gaps and patent expirations. So, new models of "risk sharing" and early-stage funding are emerging, with equity investments (often from corporate sources) tied to defined milestones and with acquisitions that are pre-arranged. This new model minimizes the need for ongoing fundraising and thereby changes the role of the typical small company CEO – from a fundraiser to a project manager. This role can be filled more easily and can also be successfully accomplished on an interim basis.

Share the Excellence

On its website, TCG offers many more White Papers giving valuable market and industry insights that will help you succeed in the constantly changing US and European life sciences industries.

Free download at

www.tcgmedtech.com