

Belgium - Life Sciences
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Life Sciences Insights

Welcome to the next Belgian newsletter for the Life Sciences industry, published by Deloitte.

We hope this will be an enjoyable and productive reading – please [contact us](#) if you have any questions or wish to discuss any of the topics further.

We wish you a very relaxing and enjoyable Christmas holiday and a sparkling 2012

Cardiac Rehabilitation: beating heart disease one step at a time

Cardiac rehabilitation has a positive effect on the quality of life of patients and reduces the chance of hospitalization or death. This is an important conclusion from a study conducted by Deloitte on behalf of the Belgian Health Care Knowledge Centre (KCE).

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Risk Sharing schemes: warranting drug effectiveness?

Patient access schemes allow drugs to be included in the reimbursement list rapidly and oblige the companies to collect data in order to be able to demonstrate a cost-effective profile for these drugs.

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Future Medicine: Can personalized medicine become a success story?

An integrated strategy for biomarker discovery and validation needs to include buy-in among stakeholders in discovery, development and commercialization through detailed and specific incentives

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Did you know?

- Deloitte writes a quarterly report on financial transactions and trends in the life sciences industry, with specific focus on Belgium
- Deloitte issued a paper on "R&D value measurement: Is R&D earning its investment?"

- Deloitte sponsored the Financial Times annual pharmaceutical and biotechnology conference
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Cardiac Rehabilitation: beating heart disease one step at a time

In collaboration with the Belgian Health Care Knowledge Centre (KCE), Deloitte conducted research on the clinical effectiveness and utilization of three different types of cardiac rehabilitation in Belgium. The report resulting from this research was published on October 27th 2010.

With cardiovascular disease being the most prevalent cause of death in Belgium, cardiac rehabilitation is an important topic. Cardiac rehabilitation aims to reverse the adverse pathophysiological and psychological consequences of cardiac events and to prevent the occurrence of further events.

The report concludes that exercise has a positive effect on the quality of life of low and average risk heart patients. Exercise also reduces the number of hospitalizations and deaths. Multidisciplinary treatments (defined as treatment by a multidisciplinary, coordinated team) involving exercise also have proven positive effects. However, when compared to exercise-only programmes, no significant outcomes emerge.

Nonetheless, it was found that one in three patients did not follow any rehabilitation programme. Less than half of the patients started multidisciplinary rehabilitation, and for 10% of them the therapy was restricted to one session after hospitalization. Elderly people and women hardly follow any multidisciplinary rehabilitation, the report concludes. Another remarkable factor was the distance to a recognized treatment center: patients living in a location deprived of a rehabilitation center almost never follow heart rehabilitation programmes after hospitalization. Reasons stated for this situation include: lack of time, lack of transport means and the distance to the rehabilitation centre.

Recommendations regarding good clinical practice include the development of patient-specific exercise programmes, matching the patients' risk profile. The programme should be spread over several months and should be organized in the vicinity of the patient's home and not just in the recognized centres. Furthermore, general practitioners should raise patients' awareness of the importance of exercise. If patients refuse or fail to comply with the proposed programme, the reasons should be systematically investigated in order to convince patients to follow the programme or to discuss potential alternatives with the patient. On top of this, life-long follow-up by the treating physician should ensure the upholding of good habits in patient behaviour.

You can find the full report here in [Dutch](#) or in [French](#)
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Risk sharing schemes: warranting drug effectiveness?

Information asymmetries concerning drug cost-effectiveness make the reimbursement of a new drug a risky enterprise. Patient access schemes can help mitigate this risk to the provider by transferring part of the risk of outcome ineffectiveness to the pharmaceutical company producing the drug. The additional information obtained through the wider use of

the drug can then be used to assess the cost-effectiveness and consequent measures concerning reimbursement can be made in order to ensure efficient allocation of the provider's resources. This can have positive consequences for patients (faster access), pharmaceutical companies (faster authorization) and payers (risk sharing).

What are patient access schemes?

The reimbursement of a new drug involves a financial risk for the provider (most often the governments, in the US private insurers as well) if the cost-effectiveness cannot be proven before introduction to the market. Patient access schemes allow pharmaceuticals to convince providers to offer the drugs to patients by sharing part of this risk. The sharing of the risk can take many different forms but the most common are financial based and outcome based schemes.

For example (of a financial based scheme), a drug could be allowed to be offered as a treatment option and reimbursed by the provider. This way as more patients have access to the drug, more evidence about the drug's cost effectiveness becomes available. This new information is then used to (re)assess the cost-effectiveness of the treatment in pre-identified intervals (every year, every 3 years etc). If it turns out that relative to existing options or to pre-specified thresholds this drug does not provide a gain, the drug is no longer reimbursed and the pharmaceutical company can be required to intervene in the acquired additional cost for the provider. Hence patient access schemes are a form of warranty the pharmaceutical company offers on the quality and effectiveness of their new products

The discussion on the effectiveness of the patient access schemes is still ongoing. In the mean time NICE has established a special unit to organize and set up patient access schemes agreements with the pharmaceutical companies (PAS Liaison Unit - PASLU). The chairman of NICE Sir Michael Rawlins recently argued that patient access schemes are too difficult to run and that the pharmaceutical companies should be providing discount on the prices of their drugs as they become available in the market in order to curb the cost-effectiveness issues their products may face.

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Future Medicine: Can personalized medicine become a success story?

Targeted therapeutics is a class of molecularly targeted drugs that attack disease-specific molecules associated with the causal pathway of disease. These agents are highly specific in terms of efficacy and the mechanism of action is highly localized and focused on a target receptor (thereby avoiding systemic side-effects). A key component of targeted therapy is a 'companion diagnostic', a test that can be used to stratify patient populations and identify groups that are most likely to respond to therapy. Examples of targeted therapeutics are Herceptin (oncologic from Roche / Genentech) and Gleevec (oncologic from Novartis).

Dwindling development pipelines, generic erosion, and overcrowded therapeutic areas are some of the key factors accelerating the need for life science companies to target genetically specific patient populations. The promise of targeted medicine and the associated systemic benefits have been touted for several years with relatively few examples of targeted medicine as a commercial success story. This is partly due to the fact that external stakeholder groups (e.g. Payers, Regulators and Government) are not aligned with enterprise and industry-wide approaches serving to fuel development and adoption of personalized medicine. On the other hand, Pharmaceutical companies that have embarked on this journey have realized a confluence of internal barriers preventing the discovery and development of targeted drugs. These barriers include the inability to recognize and therefore improve fundamental operational capabilities, outdated governance and collaboration models and appropriate incentive structures for siloed functions to work together. Despite these hurdles, and now more than ever, targeted medicine is situated to

benefit significantly from a set of complimentary trends including scientific advances in genetic / genomic profiling technologies, consumer driven healthcare and adoption of healthcare information technology, all of which is refocusing the spotlight on personalized medicine programs and prompting secondary strategies for new Pharma IP.

Specifically, an integrated strategy for biomarker discovery and validation needs to include buy-in among stakeholders in discovery, development and commercialization through detailed and specific incentives to promote cooperation and collaboration. Simultaneously, Life Science companies must realize that by developing and implementing a thoughtful targeted medicine strategy that includes R&D data transparency, Pharmaceutical industry will inevitably influence external stakeholders and facilitate changes in reimbursement, regulatory guidelines and policy development.

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Did you know?

Deloitte writes a quarterly report on financial transactions and trends in the Life Sciences Industry.

Some key transactions and trends:

Recent transactions involve Innogenetics and Movetis; recent trends include a 54% increase in M&A value and the intention of Belgian government to raise quotas of cheap prescription drugs for GPs

You can find the full article [here](#)

Deloitte U.K. released a new study on R&D value measurement.

This article was developed in collaboration with Thomson Reuters, and looks at how pharmaceutical innovation is facing a fundamental productivity challenge. You can find the full report [here](#)

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