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Pharmaceutical market at a turning point: PLCD Spring Meeting

By Ute-Gisela Minnerop

The Pharma-Lizenz-Club Deutschland (PLCD) held its Spring Meeting in Heidelberg, where the discussion was all about business development in the light of AMNOG – Germany's new law on realignment of the pharmaceutical market. Some 250 PLCD members convened for an in-depth exchange of opinions on future business models for pharmaceutical companies and on the implications for the goals and methods of business development.

Participants had an opportunity on the first day to supplement and refresh their knowledge in practical workshops, with topics including financial assessment of licence projects, bidding procedures for rebate contracts and risk analysis of licence projects, as well as useful tools for negotiations. The second day focused on the future, with emphasis on the implications of the new statutory arrangements, including early benefit assessment and, arising from this, pricing of drugs under AMNOG.

Keynote addresses

Dr Eckart Würzner, Mayor of Heidelberg, opened the meeting by saying the town was a key medical location, with the local BioRN Cluster prominent in cell-based and molecular medicine. Under the heading 'Tech transfer 2.0 – efficiency from critical mass, active coaching and solution-driven scouting', Dr Christian Tidona, Managing Director of the cluster, addressed questions such as: Which factors impact on decisions about projects and locations? What implications are associated with the accelerated generation of knowledge? Are we succeeding in applying this knowledge early for new drugs to allow for medicinal personalisation?

Along the value chain, new rules become

established for cooperation in research and development, to give patients access as early as possible to innovative drugs, diagnostic tests and services. Personalised medicine was identified as an important future trend.

Thomas Milz, Director, Strategic Projects and Market Access, UCB Pharma, presented an overview of the future importance of market access in the pharmaceutical industry. He outlined the growing influence of statutory health insurers, public authorities, Germany's Institute for Quality and Efficiency in Healthcare and the Federal Joint Committee (G-BA) on the healthcare market. The market access function, new in many companies, will act as a control tower to provide guidance in the confusing landscape of these new players.

The talk 'Sharing best practice – business development deals at Roche' given by Dr Michael Motz, Director, Business Development, Roche Pharma, gave practical insights into Roche's deal-making. The firm is backing, among other things, personalised medicine and collaborations with biotech firms. On the big pharma side, there is sufficient interest and capital for cooperative schemes, so that effective molecules from biotech research can be developed to market maturity. The contracts increasingly include earn-out clauses, whereby differing expectations of future success are accounted for and a share of the purchase price is paid depending on the results achieved.

Panel discussion

A new feature, which highlighted the diversity of opinion, was the panel discussion. Chairman of PLCD's Board, Dr Hans-Joachim Egly of UCB, had addressed the members in advance by a video message and the conference participants were asked for

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opinions on the issue: What might be the significance of business development for a new business model and the future of pharma? Their contributions indicated how forward-thinking the PLCD's members are in dealing with the new statutory requirements under AMNOG, with further cost-cutting, difficult market access and the lack of product innovation.

Market trends

Roland Berger Strategy Consultants examined the recent trends in the pharmaceutical industry in its 2010 study *Fight or Flight?* Stephan Danner, pharma specialist and Partner at Roland Berger, presented diversification in several dimensions as the most important trend. But is diversification really the future – a true strategic decision, or just the next fad? And what opportunities are there beyond this? The study identified three dimensions of diversification: risk mitigation, innovation and integration. Pharma companies will have to decide where the greatest potential will be – in optimising risk avoidance, in technologies for new products and diagnostic agents, or in a new business model as a comprehensive healthcare provider.

The background of the negative implications for business of AMNOG, the growing influence of statutory health insurers and other institutions, the differentiation of innovations and the trend toward early cooperation between biotech and established pharma companies, ensured that the closing panel discussions were eagerly awaited by the participants.

The panellists

The panellists included: Dr Thomas Lauscher, Managing Director at Rottapharm Madaus; Dr Michael Motz of Roche Pharma; Dr Frank Mathias, CEO, MediGene; Dr Karem Gomaa, Head, Business Development, GlaxoSmithKline, and Michael Ewers, Managing Director of betapharm Arzneimittel. Dr Hans-Joachim Egly and Stephan Danner led the panel.

In view of the current trend toward diversification, the first question was: Haven't we been here before? Back to square one?

Could this just be consultant's advice? Probably not, according to Stephan Danner – the pharmaceutical industry is subject to cycles. In simplified terms, a new cycle started with the dissatisfaction of law-makers with the cost explosion in healthcare. The outcome of the various health economy laws of the past ten years is that the pharmaceutical industry must now search for alternative business models. He asked the panellists how their companies were responding to the upheavals and how they were dealing with the new business environment.

A diverse picture

The panellists' responses showed a diverse picture. Dr Lauscher said Rottapharm Madaus, the traditional medium-sized company, had an advantage since under previous laws its business policy had become: dump statutory health insurance – let's go for individual patient-as-payor products. This contrasted with a statement from Dr Motz as representative of big pharma: "Roche has identified three growth areas: personalised medicine (innovative therapeutic agents tailored to specific patient groups), diagnostics and emerging markets."

Dr Mathias, as the biotech representative, stressed that because of AMNOG, a new driver is emerging in Germany that has long been around in other countries such as the UK and Scandinavia. "Germany is acting surprised, now that scientific proof of concept is no longer enough, and commercial proof of market is what matters. Just as in the automotive sector, we will have fewer players in future. We biotechs work maximally up to early clinical development and then hand over our projects to the big pharma generalists, who take care of registration and marketing."

At GSK, diversification is being pursued alongside strategies that nourish legacy products and stabilise their sales revenue. Dr Gomaa is convinced that established, familiar brands continue to possess value. Brands built up over time, such as aspirin, explained Dr Egly, demonstrate a life cycle that is much longer than the simple patent life.

The influence of statutory health insurers on product pricing must be taken into account. The fact that insurance payors,

through rebate contracts, now have full transparency on manufacturing costs and margins, was pointed out by Michael Ewers. With regard to emerging markets he remarked that it is important to distinguish between regulated and non-regulated markets abroad.

Change for the future

On the question from Stephan Danner as to how future activities in business development would change, the panellists' views reflected the various company types. Also, outside Germany, for example in Switzerland, market access has arrived, so the influence of statutory health insurers and other institutions gains increasing importance. Therefore, dynamic pricing strategies should be considered when assessing licence projects.

Although firms in the biotech sector want to partner in early-stage development, their lean structures can make it difficult even to host a due diligence meeting for a delegation of, say, 30 people from big pharma. This presents a challenge, if only for organising cooperation.

There is also uncertainty when drafting contracts; options must be considered at a time when the outcome of the product development and the course of business are still uncertain. The contracts need to take account of a range of modalities that can be difficult to anticipate. Other possibilities might be found in cooperation between the big pharmaceutical companies and producers of generics, or a focus on products for attractive niches, or on orphan drugs and on diagnostic agents as tools in personalised medicine.

What next for AMNOG?

The consensus of the conference was that, good or bad, AMNOG is here to stay. The biotech companies see it as an engine for innovation with clear benefits; for sales and marketing, it means fewer samples and visits to doctors and more evidence-based medicine. Success is no longer guaranteed by the strength of the field force but by demonstrably innovative drugs. Plenty will change; new target groups and decision-makers will adopt the modern concept of additional benefits. New research approaches and social perspectives will be considered and AMNOG will lead to a genuine paradigm shift. ■



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