



PREFACE

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Dear reader,

In this issue the following content could be of interest to you:

Page 1 "HCM goes USA" → Since September 2014 HCM is also present on the American pharmaceutical market!

Page 2 "strategic purchasing in the hospital" → Learn about the supply structure in the German clinical landscape, in order to be able to position clinical products selectively!

Page 3 The HCM filed 4 NUB applications for companies → Until the end of March next year, additional compensation can be applied for. These can be reimbursed in addition to the DRG budgets!

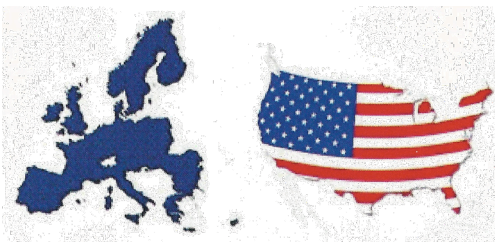
Page 4 „Marketing and sales at the interface ambulant/in-patient: Synergy potential in inter-sectorial care for more sales! → Why is it especially important for pharmaceutical companies to not view target groups in the ambulant and in-patient care sector separately?

We will gladly discuss current and especially relevant topics and developments with you. We will analyze the individual implications they will have on you and your business.

Dr. Frank Birnbaum and Dr. Dieter Schmitz and the whole HCM Team

HCM goes USA

The HEALTHCARE MANUFATUR GmbH in the meantime is looking after an increasing number of new American customers, who wish to launch their pharmaceuticals and/or medical products in Europe and the German market.



Vice versa, the HCM supports start-up companies out of the biotech sector in Germany, who wish to place their products on the US market. However, both markets need to be looked at individually and approached differently. This applies to market access strategies and also to the operative marketing of the individual product.

Therefore, it was very important to HCM to build up a bridgehead with pharma colleagues, who have expertise in US market and who know the differences to the European market.

Since September 2014, the HCM is officially being represented by MPC (Merrifield Pharmaconsulting LLC), which is located in Mt. Pleasant in South Carolina. MPC is specialized in the support of KMU's and their business development strategies in other international markets.

**MERRIFIELD
PHARMA
CONSULTING LLC**

This includes among other things in the USA:

- Market and potential analysis
- In and out licensing of products
- Support of due diligence processes
- Development of go-to-market strategies
- Market access, pricing and reimbursements strategies
- KOL targeting
- Brand planning support

The MPC thus completes the HCM portfolio. It offers international oriented companies, or those who want to become international, competent contact persons with local expertise on both sides of the Atlantic. These are able to provide complex business development strategies and solutions from a single source.

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Strategic purchasing in the hospitals

Germany, with its 2000 hospitals, who are funded by a variety of bodies, offers a full coverage care near to home. Many clinics are fighting for economic survival, since there is an oversupply in the German hospital market. The number of clinics run by municipalities has decreased by 24% in the last 10 years and the number of hospitals operated by non-governmental charitable organizations declined by 15% in the same time period. By contrast, the number of hospital treatments increased 25% in the last 10 years. In order to live up to the challenges, that complex competition and an increased number of hospital treatments imply, efficiency improvement is necessary. One possibility for efficiency improvement is, that hospitals affiliate with a private purchasing group (EKR). Purchasing groups have had an increase of 30% in the last 10 years.

Strategic purchasing in the hospital is becoming increasingly important. However, special legal requirements need to be considered, and these can vary greatly, depending on who operates the hospital.

- Public run hospitals are normally subject to procurement law (VOL), a complex legal field whose goal is the profitability and the cost effectiveness by secured coverage. The thresholds for delivery and service performance lie by a net value of € 200 000, which are quickly met by a product reference per year. The tendering procedures after VOL (ex. EKK) take place in the form of a public invitation to tender.
- Non-governmental charitable run hospitals are organized collectively.
- The privately held hospitals have centralized purchasing structures.

The objective for each EKR membership is the reduction of material costs and community costs. Price benefits are achievable through the bundling of sales. Next to A products, B-/C articles are being negotiated simultaneously, which otherwise due to lack of capacities could not be negotiated by the individual pharmacies. As a result, sales activities are more focused and sales volume can be planned more accurately in the industry.

The purchasing groups differentiate themselves in the following characteristics significantly: **Legal form and membership structures, financing, goals, purchasing volume, co-determination rights of members, exclusivity, Product- and service agreements, terms of condition, compulsory tender process or willingness, liabilities**

Purchasing groups usually have their own procurement controlling and evaluation of suppliers with a corresponding prioritization. The aim of purchasing is to establish, clear and uniform processes and procedures. The Level of success in purchasing is being measured through specialized clinic / EKR controlling for example with the quota of how well the framework agreement is being met, the number of automatized ordering processes, supplier deadline compliance, return rate of products, etc. Depending on the purchasing type, the EKR are financed over the membership fee, or over expense allowances from the industry.

Typical points of intersection in strategic purchasing are:

- Introduction of E-procurement
- Standardizing of products and suppliers
- Cost optimization
- Saving potentials
- Supplier management
 - Selection
 - Negotiation of contracts, contract conclusion
 - Supplier unbundling
 - Controlling and Tracking of contractual performance
 - Evaluation of suppliers
 - Supplier quality management
 - Collaborations for the future
- Cost-benefit assessment for drugs in hospitals
- Quality management
- Optimization of logistic processes
- Electronic billing/online ordering
- NUB-application
- Preparation and implementation of tender procedures
- Consignment warehouse, monitoring and implementation



Clinic Pharmacies

Meanwhile pharmacies are also included in the strategic purchasing process. Here, it is important to note, that in the last 10 years the number of clinic pharmacies sank by about 16%, this is due to economic pressure, pharmacy mergers and the centralization of process procedures. The pharmacy supply chain is compulsorily a separate part in the procurement process, since the German medicinal law (Arzneimittelgesetz & Apothekengesetz) dictates, that medicines available on prescription only, may be dispensed to doctors and patients exclusively through a pharmacist. Currently there are app. 400 clinic pharmacies and 100 clinic supply pharmacies in Germany. These clinic pharmacies increasingly organize themselves in purchasing cooperatives, due to the increasing cost pressure. At present there are 20 large purchasing cooperatives (18 full-line EKR +2 clinic EKR).

In Principle there are three forms of care in the clinic pharmacies:

1. In-house clinic pharmacies
2. External clinic pharmacies
3. External clinic supplying pharmacies

The following measures can support the optimization in the strategic purchasing process:

- Increasing standardization of pharmaceuticals (medicines commission- listing of substitution and/or replacement)
- Optimization of purchasing processes
- Establishment of automated logistic and packaging
- Resolution for the expiration problematic
- Collection and updates of the inventory levels
- Bundling quantities
- Consolidation of suppliers
- IT-connection
- Risk management
- Standardized treatment processes
- Treatment pathways
- Development of apps

The managers at the Healthcare Manufaktur have long-term experience in the area of clinic management of medicinal products and pharmaceuticals. This assumes an intensive and broad-ranged knowledge of the supply structure.

The challenges for pharmaceutical companies that are successful in the clinic market, is to understand the needs of the respective clinic customer, clinic pharmacies or purchasing group and to position the clinical products accordingly.

In this connection, there are several options for the pharmaceutical industry:

1. Cooperation agreements with purchasing groups and clinic chains
2. Listing of pharmaceutical commission list
3. Product promotion in the hospital ward

Consequently it requires a strategic handling on the basis of customer know-how. HCM has already very successfully supported many companies, who were either new in the German clinical market or wanted to launch new products. Contact us, if you are also interested in a clinical service.

Cornelia Halbina

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NUB

The HCM filed 4 NUB applications for companies this year

NUBs - new examination and treatment methods (neue Untersuchungs- & Behandlungsmethoden) represent a key method to achieve additional reimbursement to the DRG system budget. Therefore, they are an important source of supplement funding for university hospitals and maximum care hospitals.

The NUB applications enable new drugs, medical products, or procedures not only a quick access to the German clinical market, but also additional reimbursement through the health insurances, provided it achieves NUB-Status 1.

This year alone, the HCM developed and coordinated the content for four NUB applications with medical professional societies and was able to place them directly in many German clinics.

- Hematology/Oncology
- Antiinfectives
- Medical processes/cells

Until the end of March next year, Zusatzengelte (ZE)-additional reimbursement will be filed for all products.

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Marketing and sales at the interface ambulant/in patient: Synergy potential in inter-sectorial care for more sales!

The German health system has capacity and budgetary potential in the areas of fusion and meshing the treatment and/or care sectors. Synergy effects can be especially realized at the interface ambulant/in patient care. The driving force here is general cost reduction, while maintaining a high level of quality care for the patients. Especially patients with diagnostic, therapy intensive and partially very complex and serious diseases need an intensive and often very costly therapy. Sometimes relapses entail secondary treatments, which in turn lead to a revenue reduction. In general, these complex therapies are initiated in the clinic, but in the further course of therapy are handed over to associated specialized outpatient units (§116b/ASV, MVZ, Ermächtigungsumbungen etc.). This trend is especially apparent in the area of oncology and other highly specialized Therapy areas.

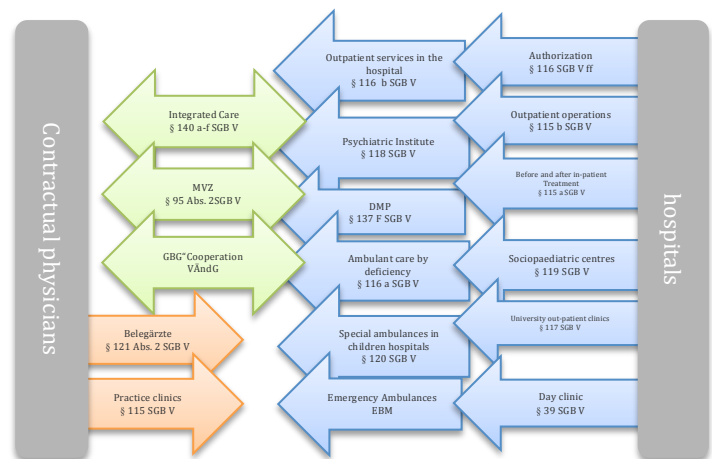
The DRG-System has two effects in the hospitals, a decreasing trend in costs and the complexity effect. The decreasing trend in costs effect describes the undershooting of the statutory DRG average costs. Existing organizational and performance structures need to be used optimally. Specific for the complexity effect is, that it attempts to deliver complex therapies, in order generate a higher level of earnings within the existing organizational and performance structures. As a consequence the DRG System automatically leads to a specialization and outpatient treatment. Hence, it is strategically critical that hospitals set the boundary for the sectorial limit for stationary-out patient care.

Further increase in importance is gained through various health care reforms such as the introduction of MVZ (GMG2003) medical supply centers. Since hospitals also act as the institutions responsible for Medical Service Centers, they can organize their inpatient services themselves. This is complemented through the opportunities associated with the integrated care contracts.

In addition the GKV-WSG (2007), the German law for enhancing competition in the statutory health insurance sector and the GKV-VStG (2012) a law to improve the supply structures in the statutory health insurance sector, have further promoted the interface through the reform of the §116b SGB V. Since then, the hospital is not only suitable for ambulant service performance but with the ASV, specialist specialized care, an own pillar in the Healthcare landscape has been established. Hospitals and practicing doctors are now obliged to cooperate.

Furthermore, the effects of the new law, to improve the supply structure in the statutory health insurance sector, will lead to new options around inter- and trans-sectorial care.

The complexity and the design variety in-patient care and the interface ambulant/in-patient, is schematically illustrated in the diagram below. An important aspect for pharmaceutical companies or rather all healthcare market participants is, which are the relevant reimbursement and medical care pathways with regard to sales and the use of a medication or which method can be effectively stimulated. This is not only split up into the areas of the DRGs and §6KHEntG-remuneration for innovations and the corresponding reimbursement management of NUB and ZE- remunerations, but especially in the area of the EBM and the redesign thereof. This is extremely relevant in the area of personalized medicine, gene and molecular diagnostics and possibly enables access to new therapeutics in the in-patient care daily business, due to lack of reimbursement possibilities in the DRG framework.



For the targeting of our pharma-customers, it is even more important, to not only to view these target groups, hospitals and ambulances separately and to use pathway analysis and reimbursement evaluations for possible market explorations. In addition, this has further direct sales implications, such as the triggering of spillover effects from in-patient to ambulant care.

The HCM can offer you analysis and training services. Beyond that, we can set new impulses and offer a deeper knowledge in the areas of clinic/key account management. Do not hesitate to ask our specialists for relevant reference projects and current training possibilities for management and sales.

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