



## PREFACE

EDITION 2 / 2014

**Dear Reader,**

**More individuality.  
More value.**

Our guiding principle for successful, strategic and hands-on brand management!

We are equally "at home" in the areas of Oncology, anti-infectives, orphan diseases, as well as in important economic areas and/or chronic diseases such as asthma/COPD, rheuma and CNS diseases. Whether international start-up, medium sized company, or international player: In the



end, what connects us all together, is the passion for finding the best, individual and multivalent way in the lifecycle.

The Healthcare Manufaktur through its specialists and generalists is a "participating" consultancy: Always at your side, experienced in finding marketing and sales solutions to problems in your daily business.

We will gladly speak with you about current and especially relevant developments and the individual implications it will have on you and your product.

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

It is from this time, with more than 30 accompanied these papers, as well as being part of own teaching assignments, the HCM has been able to develop a network to various universities and colleges, such as the Hochschule Fresenius and to the professorial chair for medical management Prof. Wasem in Duisburg-Essen. The focus of cooperation lies in medical management and healthcare economics, as well as access studies and/or qualifications.

The HCM integrates internships within the company business, ranging from study groups to (co) initiation and accompaniment of BA/ master thesis to current issues in the healthcare industry.

### **Current HCM cooperation's with Universities:**

- Hochschule Fresenius
- Hochschule Ludwigshafen am Rhein
- EC Europa Campus Mannheim
- Rhein-Ahr-Campus
- FH Köln
- Professorship Medical Management Prof. Wasem University Duisburg-Essen

With this, the HCM is able to offer numerous interesting options to its customers with the dynamic and the variety of college and university chairs, with their highly qualified personnel and last but not least graduates with practical experience. This service offering is becoming increasingly popular with industry customers – feel free to ask us more about it. We will gladly discuss examples and give you real world business cases.

## **HCM university cooperation**

The intensive relationship to universities and students has a long tradition for HCM. Already, during the time with Pfizer, the HCM management was highly involved with studies of diploma students, bachelor and master students and/or graduate students. The HCM always appreciated the great commitment and the strong will to learn that these young future managers brought with them.

Dr. Dieter Schmitz

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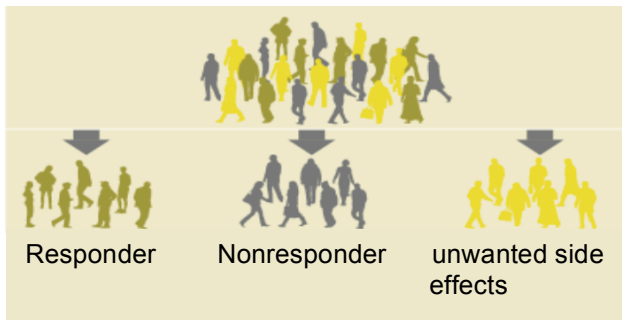
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## Personalized Medicine – A new area with great potential!

The Human Genome Project, with the decoding of the human deoxyribonucleic acid DNA in the year 2003, marks a cornerstone for genetic testing. Personalized Medicine has profited greatly from this event. In personalized medicine, genetic diagnostic tests are used to determine whether a patient would benefit from a specific drug therapy. Especially in the area of oncology more and more medicines are being approved, for which such a genetic diagnostic test is required.

Meanwhile, there are 36 substances for which personalized medicines can be assigned. The associated genetic diagnostic tests on the one hand help patients to get a targeted therapy, but on the other hand help to save costs for the GKV (statutory health insurance), since ineffective therapies can be avoided.

### Optimal therapy for each individual Patient



Source: Hessen Biotech (Hrsg.) (2011). Personalized medicine in Hessen.

A classic example for personalized medicine is Herceptin (Indication: Mamma carcinoma). Before this medicine may be applied, a genetic diagnostic test must be performed, to determine if a patient has a HER2-positive tumor. If this is the case, a medicine may be applied. The advantage hereby is, that the medicines act highly specific and therefore improve the course of the therapy.

Areas that can be associated with personalized medicine are:

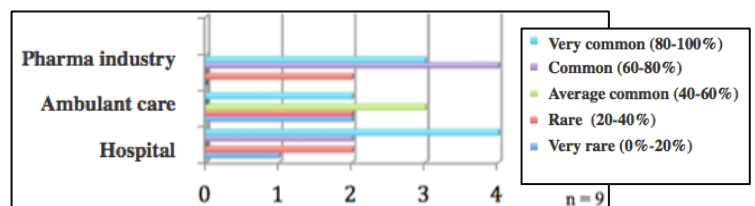
- Companion diagnostics in various indications
- Gene expression analysis, with which the probability for a recurrence is determined (f.ex. Oncotype DX),
- Genetic tests for determining the metabolism type,
- Pre-implant diagnostic is helpful to decide whether a generated embryo should be implanted into the uterus.

While the reimbursement for pharmaceuticals is clearly defined, this is not the case for genetic diagnosis testing. In the practicing field, genetic diagnostic testing can be applied for on the Basis of § 135 Abs. 1 SGB V. In the year 2013, two applications were filed for with the GKV-Spitzenverband for evaluation according to § 135 Abs. 1 SGB V. The results are not yet available. Furthermore, tests can be billed for according to fee schedule numbers 11320 – 11322 of the EBM.

In the inpatient sector, genetic diagnostic tests can be applied for as NUBs (new and innovative therapies and methodologies) according to §137c Abs. 1 SGB V. However, until now such applications have been rejected. Consequently, the only way to currently bill genetic diagnostic tests is according to the DRG flat rate per case compensation, but these are partially very expensive, so that the lump compensation would not be cost-covering.

As a result, genetic diagnostic tests in the area of personalized medicine are hardly used in the inpatient sector.

The area of personalized medicine is still in its relatively early stages, but it shows great potential for future development. How this potential will be used, is influenced by a variety of factors such as the reimbursement in genetic diagnostic testing.



Expert assessment of the distribution, of personalized medicine in the pharmaceutical industry, in ambulant care, and in the hospital.

Source: Bachelor study topic: "Personalized medicine from the perspective of the pharmaceutical industry by means

The HCM has extensive knowledge in the area of personalized medicine and can optimally support and advise you, for example in answering market access questions, reimbursement specifics, and pathways (NUB, DRG, EBM).

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## Intelligent Apps

At the moment there are about 15 000 patient healthcare-apps in the German market with a rising trend. For lay people, it is extremely difficult to get an overview and to determine, which of these numerous apps are really useful. For pharmaceutical companies apps are becoming increasingly popular as a sales and service tool. However, in these cases the content is usually product specific. Customer interaction or reimbursement issues are often not addressed.

HCM offers the service and the know-how, to develop tailored, intelligent and customer interactive apps for companies.

### Example-app:

The HCM-App is amongst other things an **additional fees (Zusatzengelt-ZE) calculator**, which is a unique and innovative tool for the field force. With this tool, the company can autonomously execute the reimbursement calculations for various indications of a specific drug in the clinic.

The HCM app shows different scenarios, including the dose related reimbursement for the drug and selective ZE capable competitors.

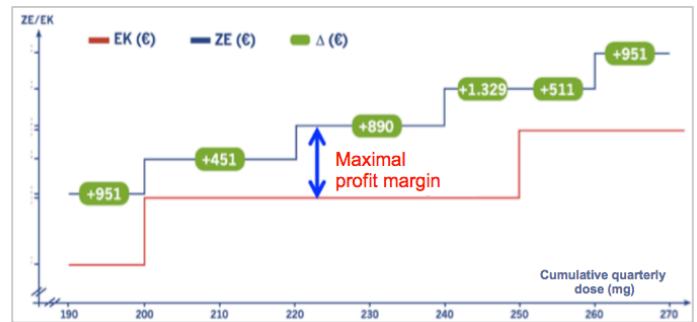
Through interactive input options such as price and dose, different profit situations can be illustrated and simulated, for the clinic, for the manufacturer of a specific drug, or for competitor products.

In the start-frame name, therapy, size, weight, dose, cycles per quarter can be entered. The administered total dose in milligram is calculated with the help of size, weight and dose. In addition, if you enter the number of cycles per quarter, the app calculates the total costs and shows the ZE revenues.

Patient	Sabine P.	Therapy	
Size (cm)	170		
weight (kg)	70		
Dose (mg/m <sup>2</sup> )	xy	Total dose (mg)	xy
Cycles / Quarter	xy		
Price (€)	xy	Total Price (€)	xy
		ZE (€)	xy

### Start up screen

After the data is entered, a new screen appears, which shows how the profit margin changes. This depends on the previously entered price.



### Profit rate within a dosage category

Thus, one quickly gets an overview, in which area the marginal costs are and which profit margin can be reached. This is an entirely new health economic presentation method for medical controllers, pharmacists and especially for clinical users.

### Advantages app:

Quarterly optimization:

- ZEs can be billed quarterly (max. profit margin).
- Entering dosage amount per cycle.
- Number selection of cycles.
- Automatic calculation of total dosage in mg and the total price.

Patient	Total dose (mg)	Cycles	Total dose (mg)	Total price (€)	ZE - EK (€)
Sabine M.	xy	8	xy	xy	xy
Max	x x xy	x x x x	x x		
Min	x x x x	x x x x	x x		
	Quarter 1	Quarter 2	Quarter 3		

Cycle Overview through arrow movement:

- Display of total price.
- Decision support with therapy selection and possible admission.

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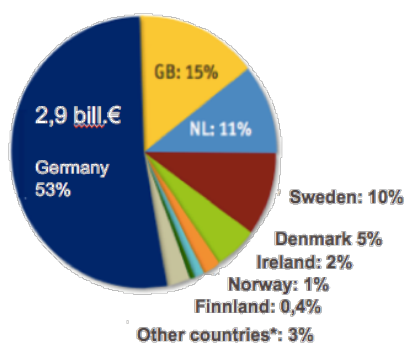
## Parallel imports- Risks & side effects

Parallel imports in the pharmaceutical market are being encouraged since the year 1990. From this time comes the so-called "Parallel Import Quota", which guarantees importers revenues and forces pharmacies to meet a 5% import portion of total sales with ready-made pharmaceuticals. The reason for the support, are the saving potentials, since pharmaceutical companies can use price differentiation and sell drugs considerably less expensive to neighboring countries. Importers use these price differentiations (=arbitrage) and sell original products presumably less expensive than the producing pharmaceutical companies.

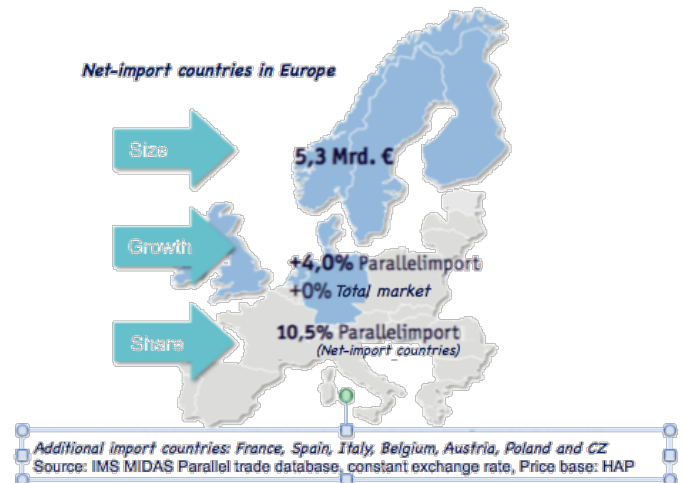
A "Preisabstandsklausel" price gap provision is supposed to ensure a minimum saving: Imports, which are 15 Euro or 15% less expensive than the original product are used to calculate the import quota. As a consequence of this bizarre regulation, the importers have a focus on high priced products such as cytostatics.

The price differentiation above 100 Euro is limited to 15 Euro. In this high price sector is consequently the highest profit for traders. A price comparison between imports and original products is nearly impossible, since there are different rebates and individual price negotiations (AMNOG § 130b SGB V) between the insurance companies and the pharmaceutical companies. Experts see this topic as very critical, especially since the "VfA", the German Association of Researching Pharmaceutical Manufacturers says, that the savings potential is less than 100 million Euros.

Parallel imports in value  
Total market: 5.5 billion Euro  
MAT 09/2012



The predictability of production quantities for complex manufacturing drugs such as cytostatics is becoming nearly impossible, since the rate of parallel imports within the field of the practicing doctors is steadily growing. However, especially with vital indications planning security for the producing company is absolutely necessary in order to secure the supply guarantee for patients.



Research and surveys done by HCM showed, that the imports are actually not less expensive than the original products.

Problems especially arise, when a doctor directly prescribes an import product. The pharmacies would have to calculate, which import can be used to meet the quota.

- 25% of all oncologists directly prescribe products out of parallel imports.
- Pharmacists see an increase in supply gaps and in the delivery time for drugs.
- Pharmacists see imports critical.
- For vital indications such as cytostatics
- Pharmacists do not want to rely on importers for a reliable delivery.
- Patients do not tolerate import products well.
- There are often product recalls, because of errors in the package inserts.
- The pharmacist manually has to calculate the price difference to the prescribed import product.

It is incomprehensible, why the lawmakers support the importers. Experts have long been calling for an abolition of parallel imports and the price gap provision. The role of the importers should in any case be reconsidered – especially with regard to medicine supply reliability.

Maurice Neuwirth

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