

The Reimbursement and Funding of Inpatient Medicines

- A comparative Analysis of Inpatient-Drug-Reimbursement-Systems in Germany, England (UK) and France from a socio-scientific Perspective -

by

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(ABSTRACT)

Introduction: With the introduction of prospective payment systems based on case-mix the compensation for drug costs is built into patient-classification systems or so called DRGs. Since these systems are constructed not very flexible, the inflexibility may cause a delay in the drug's uptake in the hospital practice as well as a lack of appropriate funding. In order to compensate for that inflexibility supplementary and alternative funding measures for drugs were established in Germany, England and France. These funding measures as well as patient classification systems are assumed to be determined by the influence of particular priorities which are displayed in diverging regulations and decision outcomes. The funding and reimbursement processes as well as corresponding decisions and regulations are more or less arbitrary and priority-driven among Germany, England and France.

Methodology: An explorative research design was chosen. To collect information in total 14 experts have been recruited who have an insight into the clinical practice in the examined countries. Semi-structured expert interviews, documents and scientific articles provided insights with regard to an initial concept of inpatient-drug reimbursement-barriers and the actual practice in German, British and French hospitals. Stern's and Holder's (1999) appraisal framework for regulatory systems was used to assess the institutional design and regulatory processes.

Results: The analysis revealed different qualities of regulation depending on the level of decision-making, the involved stakeholders and their competencies as well as the domain decisions and regulations are made for or in. Thereby, drugs reimbursed as part of activity-based hospital budgets do not face significant barriers to be administered and funded. Although the regulatory setting is not very transparent in all three of the countries, decisions can be retraced, are predictable and not very arbitrary. Differently the situation turned out with respect to supplementary and alternative funding of drugs. Thereby major regulatory deficits occurred in particular with regard to the granting of funding for innovative drugs in Germany and in England in general.

Conclusion: The qualitative ranking from A to E was applied to indicate supporting and constraining features and characteristics of the different hospital remuneration. In terms of the most favorable conditions a ranking of A was given. An E-ranking in contrast implies that the level's specific regulatory setting causes a highly unfavorable and uncertain situation for the new drug's uptake in the daily hospital practice and its secured funding.

Regulatory and decision-making systems turned out to be comparable well in all three of the countries. Thereby, France turned out to be the most favorable country in terms of providing patients in need quickly with drugs and allowing manufacturers to earn a reasonable rate of return. Except for the granting of supplementary innovation remuneration, which turned out to be quite arbitrary, also Germany has a good regulatory framework in place which is acceptable to all involved stakeholders. The most urgent need for improvement in the regulatory system was discovered in England. There, highly unfavorable conditions, with regard to alternative and supplementary funding endanger the universal and equal access to care for patients in need and do not allow pharmaceutical manufacturers and hospitals for an acceptable extend of predictability concerning a drug's funding.

*patient-classification / supplementary funding

Key-Words: *Activity-based financing; Diagnosis-related groups; Prospective payment system; Patient-classification system; Inpatient reimbursement regulations*

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TABLE OF CONTENTS

ABSTRACT	II
ACKNOWLEDGEMENTS	III
LIST OF TABLES	VI
LIST OF FIGURES	VII
ABBREVIATIONS	VIII
1. INTRODUCTION	- 1 -
2. THEORETICAL APPROACH AND METHODOLOGY	- 3 -
2.1 THEORETICAL APPROACH FOR THE COMPARISON AND EVALUATION OF INPATIENT-DRUG REIMBURSEMENT REGULATIONS AND PROCESSES	- 3 -
2.2 STUDY DESIGN	- 7 -
2.3 DATA ANALYSIS	- 10 -
2.4 SCOPE AND LIMITATIONS	- 12 -
2.5 STRUCTURE OF THE THESIS	- 13 -
3. FACTUAL INFORMATION ON PATIENT-CLASSIFICATION- SYSTEMS AND ALTERNATIVE FUNDING MEASURES.....	- 15 -
3.1 INTRODUCING ACTIVITY BASED HOSPITAL REIMBURSEMENT	- 15 -
3.2 SYSTEMATIC OF PATIENT-CLASSIFICATION-SYSTEMS – DRUG-COST- FRACTIONS AS PART OF ACTIVITY-BASED HOSPITAL BUDGETS	- 17 -
3.3 INNOVATION REMUNERATION AND SUPPLEMENTARY REIMBURSEMENT AS NECESSARY COMPONENTS OF INPATIENT-DRUG FUNDING – COPING WITH SYSTEM-IMMINENT WEAKNESSES OF PATIENT-CLASSIFICATION	- 20 -
3.3.1 <i>“Supplementary Innovation Remuneration” – Vanquishing the Post-Production-Phase</i>	<i>- 21 -</i>
3.3.1.1 Germany: “New Diagnostic and Therapeutic Procedures” (NUB)	- 22 -
3.3.1.2 England: “Pass Through’ Payments” (PTP).....	- 26 -
3.3.1.3 France: “Autorisation Temporaire d’Utilisation” (ATU) and “Protocols Thérapeutiques Temporaires” (PTT).....	- 28 -
3.3.2 <i>“Regular Supplementary Reimbursement” – Vanquishing Technical weaknesses of Patient-Classification Systems</i>	<i>- 31 -</i>
3.3.2.1 Germany: “Zusatzentgelte”	- 31 -
3.3.2.2 England: “Payment-by-Results-Exclusions” (PbR-Exclusions).....	- 34 -
3.3.2.3 France: “Tarification à l’Activité” – Excluded drugs (T2A-exclusions).....	- 36 -

4. ANALYSIS.....	- 39 -
4.1 FORMAL ACCOUNTABILITY	- 39 -
4.1.1 <i>Clarity of roles and objectives</i>	- 40 -
4.1.2 <i>Accountability</i>	- 42 -
4.2 INFORMAL ACCOUNTABILITY	- 44 -
4.2.1 <i>Transparency</i>	- 45 -
4.2.2 <i>Participation</i>	- 47 -
4.2.3 <i>Predictability</i>	- 49 -
4.3 PRELIMINARY CONCLUSION	- 50 -
5. DISCUSSION.....	- 53 -
REFERENCES	- 57 -
APPENDICES	- 67 -
<i>A1: Interview guide</i>	- 67 -
<i>A2: Influential Stakeholders in the different hospital remuneration systems</i>	- 75 -
<i>A3: Defining case-group prices</i>	- 80 -
<i>A4: Opportunities for Spontaneous and Unscheduled Updates</i>	- 82 -
<i>A5: Impact of NICE TAGs on PTPs</i>	- 83 -

LIST OF TABLES

Table 2.1.1: Appraisal Framework for regulatory systems	- 6 -
Table 2.2.1: List of interviewed Country-Experts.....	- 10 -
Table 2.3.1: Ranking definitions of appraisal criteria	- 12 -
Table 4.3.1: Overall Summary of assessed Findings – Patient Classification:	- 51 -
Table 4.3.2: Overall Summary of assessed Findings – Supplementary Funding	- 52 -

LIST OF FIGURES

Figure 3.2-1: Systematic of Mapping new Inpatient-Activities in Patient-Classification-Systems	- 17 -
Figure 3.2-2: Country-Overview of Reimbursement Rate Definition.....	- 18 -
Figure 3.3-1: General Course of Innovative Drugs from MAA to Financially Assured Administration.....	- 23 -
Figure 3.3-2: General Process of Negotiating Supplementary Remuneration for Innovative Drugs.....	- 24 -
Figure 3.3-3: The Long-term Financial Establishment of Drugs in Germany.....	- 32 -

ABBREVIATIONS

AFSSAPS	Agence française de sécurité sanitaire des produits de santé [French Agency for Sanitary Safety of Health Products]
ARHs	l'Agence Régionale de l'Hospitalisation [Regional Hospital Agency]
ATIH	Agence Technique de l'Information sur l'Hospitalisation [Technical Hospitalisation information agency]
ATU	Autorisation Temporaire d'Utilisation [Temporary Authorization for Use]
BNF	British National Formulary
CEPS	Comité économique des produits de santé [Economic Drug Committee]
DH	Department of Health
DRG	Diagnosis Related Groups
DTC	Drug and Therapeutics Committee
EMEA	European Medicines Agency
ENC	l'Etude nationale des Coûts national Reference Cost Study
G-DRG	German Diagnosis Related Groups
GHM	Groupes homogènes de malades [Homogeneous Patient Group]
GHS	Groupes Homogenes de Sejours [Homogeneous Hospitalisation Groups]
HAS	Haute Autorité de Santé [French National Authority for Health]
HCD	High-Cost-Drug
HCFA	Health Care Financing Administration
HRG	Healthcare Resource Groups
ICD	International Classification of Diseases
INCA	Institut national du cancer [National Cancer Institute]
InEK	Institute for Hospital Reimbursement [Institut für das Entgeltsystem im Krankenhaus]
KHEntgG	Krankenhausentgeltgesetz [Hospitals' Fees Act]
LEEM	Les Entreprises du médicament [French Pharmaceutical Companies Association]

MDK	Medizinische Dienst der Krankenversicherung [Health Insurance Medical Service]
MoH	Ministry of Health
NHS	National Health Service
NHS IC	National Health Service Information Centre
NICE	National Institute for Health and Clinical Excellence
NICE TAG	National Institute for Health and Clinical Excellence Technical Appraisal Guidance
NUB	Neue Untersuchungs- und Behandlungsmethoden [New Diagnostic and Therapeutic Procedures]
OPCS	Classification of Surgical Operations and Procedures
PbR	Payment by Results
PCT	Primary Care Trust
PPS	Prospective Payment System
PTP	Pass-through-Payment
PTT	Protocols Thérapeutiques Temporaires [Temporary Therapeutic Protocol]
RHA	Regional Health Authority
SHI	Statutory Health Insurance
UK	United Kingdom
UNCAM	l'Union nationale des caisses d'assurance maladie [Health Insurance Fund National Union]
T2A	Tarification à l'Activité [Pricing per Activity]

1. INTRODUCTION

In 1988, the European Council enacted in its Directive 89/105/EEC (Art. 6) the availability of drugs on national markets within 180 days. During that time period, a price-negotiation- approval and the product's reimbursement was thought to be granted. In the real life setting, however, it can take time until a drug will actually become part of the routine prescribing practice despite of having the required market authorization by EMEA. The delay in the actual uptake of a new drug can be caused by the time that physicians need before a treatment is common practice: the positioning of key opinion leaders; already established or potential competitors in the market, and many more stakeholders or stakeholder relations. This thesis will only focus on the decision-making processes about the cost of drugs, and in how far they will be compensated for by health care financing institutions in a country. This focus is of relevance as it will enable the analysis and assessment of the quality of regulation concerning the funding and reimbursement of inpatient medicines which are made within the context of national rules and regulations.

While a multitude of research was done concerning the marketing of outpatient drugs dealing with regulatory and decision-making frameworks and processes, the examination of regulatory environments, which determine the funding and reimbursement of inpatient drugs, has been slightly disregarded. Considering the prescribing and funding practice in hospitals date back to 10 years ago, hospitals were deemed in general as centers of excellent care and the first bastion of innovation which were benefitting in the vast majority of cases from open-ended budgets. There was a lack of consciousness concerning cost-controlling within the clinical prescribing practice. In fact, it was easy for clinicians to provide every treatment possible or to administer drugs as one was thinking best regardless the accruing costs. This situation, however, incrementally changed congruent with health care reforms taking place emphasizing the need for rational decision-making based on evidence of effectiveness and efficiency.

Hospital funding has made a paradigmatic shift from open-ended budgets to financially limited and increasingly monitored financing systems. Aiming for a more efficient provision of care, cost-containment and an improvement in quality – in the context of more and more stressed health care budgets – decision-makers of the major European countries decided to 'import' a model of prospective hospital financing based on case-mix which has been already successfully practiced in the United States and Australia, and to abrogate open-ended block contracts and budgets merely based on the length of stay. These ways of hospital funding were perceived as setting wrong incentives with respect to the generation of hospital revenues causing rather a concentration on the volume of patients treated and their longest possible stay than on the actual activity provided in a most efficient possible way. In order to accomplish that change, patient-classification systems were implemented. By means of those, inpatient activities, necessary to treat a patient, may be grouped into medically meaningful case-groups which are economically comparable. Subsequently each case-group is assigned a monetary value whereas the sum of all case-groups brought to account by a hospital sets the hospital's

total revenue budget. These case-groups were thought to be universally applied as the new measure to reimburse hospitals according to the actual activity which has been provided.

The introduction of this type of hospital financing systems, however also introduced a side effect - the delay in uptake of medicines. The compensation of drug costs had to be built in patient classification systems of hospital activities. Yet, these systems are not constructed very flexible. Consequently, patient-classification systems are not always in accordance with real price changes and improvements in therapy options. Moreover, in particular innovative drugs face problems to be mapped instantly within patient-classification systems after they have been launched. Consequently, the inflexibility may cause a delay in the drug's uptake as well as a lack of appropriate funding. In order to cope with that problem and to assure the provision of necessary treatment for patients in need, many countries were implementing additional alternative or rather supplementary funding measures.

Alternative and supplementary funding measures were individually adjusted to meet the necessity of balancing the inflexibility of classifying inpatient activities as the basis for funding hospitals. The adjustments of alternative and supplementary funding measures happened analogically to country-specific changes of DRG-systems which have been adopted in Europe from the US and Australia. Adjustments were necessary due to the different ways health care is financed in general, but also, because of diverging infrastructural circumstances, epidemiologies, and the way health care is organized and provided.

A number of studies are dealing with the adjustments and changes in terms of describing the technical design, the content, the utilization and acceptance of patient-classification systems used within the context of activity-based funding in hospitals (Guessow 2008; Fischer 1994-2007). Other studies researched the situation of providing patients in need with sufficient treatment. However, the impact of patient classification systems on the uptake of innovative high-cost drugs in the hospital setting and the measures to cope with weaknesses of patient classification have not been explored, yet, from a regulatory-political perspective in the existing literature (Chauhan&Mason 2008). Systematic and comparative research about the regulations and processes implemented in the different countries is lacking. This paper presents the result of a study which has been designed to fill this vacuum. Although comparative literature about the reimbursement of new inpatient drugs is scarce, there are national publications available. In Australia two case studies have been published in 2007 and 2009 which describe the priority-setting; funding and access to high-cost medicines in Australian public hospitals¹. In the area of oncology the difficulty of obtaining reimbursement for new drugs has been emphasized².

The aim of this paper will be to analyze and assess the differentiating inpatient reimbursement processes and the acceptability of the regulatory framework to patients, firms and governments considering the priority-driven decisions on the funding and reimbursement of inpatient medicines in England, Germany and France.

¹ Gallego, Taylor&Brien (2007 and 2009)

² Wilking&Joensson (2005); Niezen et al. (2006); McCabe et al. (2009)

2. THEORETICAL APPROACH AND METHODOLOGY

2.1 Theoretical Approach for the Comparison and Evaluation of Inpatient-Drug Reimbursement Regulations and Processes

Hospital financing accounts for a major part of health care expenditures. It was assumed that regulation and decision outcomes are not free of individual interests but significantly influenced by particular priorities dependent on decision-making stakeholders and regulatory authorities. These may differ depending on the specific institutional setting and so do regulations and decision outcomes regarding funding and reimbursement processes, decisions, and regulations with respect to inpatient medicines.

It was chosen to approach the comparison of inpatient drug reimbursement systems with a socio-scientific perspective in order to learn about how the different regulatory systems affect the uptake and administration of drugs in clinical practice. Thereby the perspective implies that a closer look at the governance elements of inpatient drug reimbursement regulations and processes is taken without following a decision-maker approach but trying to remain independent.

In order to analyze the way inpatient medicines are governed it was chosen to focus on the acceptability of the different established regulatory frameworks to patients, firms and governments. This acceptability is based on notions such as e.g. accountability, the quality of regulatory decisions and the common understanding of the “rules of the game” (NERA 1998).

A perfectly suiting theoretical and analytical framework from the area of healthcare research and policy that can be used in our study was not available. Literature which assesses regulatory structures is scarce in general and non-existent in the area of regulatory frameworks for the introduction of new and innovative inpatient drugs.

In fact, in 2006, John Hutton and colleagues were concerned with developing an analytical framework within which the different fourth hurdle systems in European countries and the applied health technology assessment methods are attempted to be described and classified in order to contribute (based on international benchmarking) to greater accountability and transparency in the area of health care regulations. Aiming for a comprehensive understanding of ‘fourth hurdle systems’ the framework refers to systems in which reimbursement decisions are made in, on a political system level and on an individual technology assessment level. The underlying objective of developing the framework was to provide an analytical tool by whose means it becomes possible to improve the knowledge of legal and political characteristics at the system level and move toward consensus in comparatively analyzing designs, operations and impacts of fourth hurdle systems (Hutton et al. 2006).

Although Hutton’s framework entails several parallel aspects and features to be researched from a socio-scientific perspective within the scope of that thesis, it nevertheless was chosen to adopt a more economic-institutional approach in order to learn about the governance elements of inpatient drug reimbursement regulations and processes. “In relation to economic regulation, governance is concerned with the way in which institutions and processes act so as to achieve a fair balance between

the interests of firms, consumers and government” (NERA 1998, p.16). Thus, instead of only describing and understanding legal and political characteristics of regulations on the system-level it is aimed to further encompass also the comparative analysis of a regulatory framework’s acceptability with respect to its government elements.

For that reason an appraisal framework for regulatory systems was found which was developed by Stern and Holder to evaluate the performance of regulatory frameworks of infrastructure industries in 6 developing Asian countries. The appraisal framework was appropriately applied in practice with regard to e.g. telecommunication infrastructures in India (ibid. NERA 1998).

Stern and Holder describe the “[...] economic regulation of utilities by covering issues such as: pricing; investment/cost of service; quality (including service standards and service obligations); and the rate or return on assets”. Thereby they understood the role of economic regulation as “[...] to incorporate such requirements in decisions affecting the variables above rather than to decide on the chosen standards or the method of regulation” (Stern&Holder 1999, p.35).

The standards which Stern and Holder applied to infrastructure industries are valid for the pharmaceutical market as well since the three characteristics of infrastructure industries which cause a need for economic regulation can also be applied to the pharmaceutical industry. Accordingly, not solely “investors in these industries [infrastructure industry] are making a hostage to fortune when they invest” but also pharmaceutical manufacturers. As in infrastructure industries pharmaceutical manufacturers are subject to “the risk of strategic behavior, particularly by governments” (Stern&Holder 1999, p.35). An example is the risk pharmaceutical companies are facing with respect to investment costs which are generated by the research and development of new drugs. Pharmaceutical companies have to invest into the exploration of a multitude of molecules, knowing that only a very small number of molecules will provide a perspective for further research. Thus, a high proportion of funds invested in research will be sunk costs. It is not self-evident that those costs are taken into account by the government in price negotiations of new drugs which make it to the market. Stern and Holder emphasize that infrastructure industries are characterized by high economies of scale. As a consequence monopoly markets can be expected. Pharmaceutical companies at the first glance seem to be active in a highly competitive market. However, specific products are intruded in quasi-monopoly-circumstances. At the time of the introduction of a new innovative drug a single research-based pharmaceutical supplier will have a patented monopoly for a certain period.

Stern and Holder accentuate that utilities and services “[...] are consumed by and necessary to the welfare of all households. Hence, the prices of such commodities are highly political [as] cost-based prices for small consumers can represent a substantial proportion of household budgets” (Stern&Holder 1999, p.35). This is also applicable to the pharmaceutical sector. The annual costs of innovative drugs are so elevated that a majority of households in need would not be able to afford them. Stern and Holder further mention that “[...] these [products and] services are critically important intermediate inputs for other sectors of the economy” (Stern&Holder 1999, p.35). Considering the

pharmaceutical market there are distinctive parallels - a productive and healthy work population is crucial for societal welfare.

The requirements for a well functioning regulatory system for infrastructure industries as defined by Stern and Holder will be translated to the pharmaceutical sector (ibid. p.38). According to Stern and Holder (1999) the regulatory system should: “ensure the efficient provision of services to consumers [...]” and “support private investment by continuing to allow companies the reasonable expectation of a normal real rate of return” (Stern and Holder 1999, p.38).

In the context of this study the requirements described by Stern and Holder can be translated in a more healthcare-specific way in order to assure the frameworks applicability to the pharmaceutical sector and hospital financing regulations. The first requirement, i.e. the efficient provision of services to consumers can be interpreted as “patient-access”. Patient access refers to a pharmaceutical manufacturer’s and hospital’s opportunity to provide patients with access to a new and effective product (Cabe et al. 2009). It is important to note that, access is not only a matter of availability of a product. Patient access exists only if a drug can actually be used by the people that are in need of it (Aday & Anderson 1974). The second requirement, i.e. the reasonable expectation of a normal real rate of return depends in the pharmaceutical sector often on price and volume negotiations for a product and the way hospital remuneration is organized. How bad or well these requirements are embedded in the regulatory system will be scrutinized by means of selected criteria of formal and informal accountability on three levels/domains, which differ in the way funding decisions are made:

- 1) Activity-based Funding
- 2) Innovation-Remuneration
- 3) Non-Activity-based Alternative/Supplementary Remuneration

Stern and Holder identified six interrelated criteria “which characterize the main governance elements of economic regulation” (1998). Three of those criteria can be classified as formal accountability aspects of regulation which primarily relate to the institutional design:

- 1) Clarity of roles and objectives
- 2) Autonomy; and
- 3) Accountability.

Three other criteria, which relate to the regulatory processes and practices, can be classified as informal accountability:

- 1) Participation

- 2) Transparency;
- 3) Predictability.

The six criteria describe the “likelihood of the regulatory framework being acceptable to firms [and] customers [...] in the medium to long term. Importantly, they also cover the mechanisms available to firms or governments if they are unhappy with the way in which regulation is being carried out” (Stern&Holder 1999, p.42). The quality of regulation and the consistency in decision-making processes with regard to the notions of formal and informal accountability will be evaluated by means of merely five of these criteria which are stated and explained in table 1.1. Autonomy will be excluded as it would shed the focus disproportionately strong on the examination of micro-level decision-making processes and within health care is easily linked with ‘professional autonomy’ , which is not needed with respect to the macro-level and institutional problem focus of the thesis. Yet, autonomy will be reviewed in the examination of the level of independence as well as the role regulating authorities and decision-making institutions play will be scrutinized from an institutional triggered perspective in the context of the “clarity of roles and objectives” analysis and when dealing with “accountability”. Thus, there is no necessity with respect to the problem focus of the thesis to go deeper into details such as the appointment of employees and whether the funding of involved stakeholders are a matter of revision.

Formal Accountability	
Clarity of Roles and Objectives	Clarity should help to make regulation more effective by removing any possible confusion about which functions are carried out by regulators. Both accountability and predictability will be significantly enhanced if regulators’ objectives are clearly stated, enabling them to be challenged if they depart from these objectives
Accountability	Accountability requires that regulators’ decisions can be challenged in an effective way. The regulator should also be accountable for any failure on his part to fulfill his statutory obligations
Informal Accountability	
Participation	Participation occurs when all relevant parties contribute effectively to the regulatory process. Participation should be meaningful, in the sense that participants must have a genuine chance of influencing decisions before they are made
Transparency	Transparency should be a requirement on regulators to explain their decisions and processes. Should reduce the likelihood of unfairness or incompetence. In addition, transparency is crucial for ensuring effective accountability, since regulated firms and others will have a better understanding of regulators’ reasons for making certain decisions, and will therefore be more confident in their ability to challenge some or all of those reasons. Transparency will help to secure more effective participation
Predictability	Firms should be able to be reasonably confident that the “rules of the game” will not suddenly change. They should provide the manufacturer with the opportunity of planning security and should exclude any arbitrariness from the decision-making

Table 2.1.1: Appraisal Framework for regulatory systems

Based on this approach in which the formal accountability structure (clarity of roles and objectives and accountability) and informal accountability structure (participation, transparency and predictability) are addressed the research objective of this paper is

To explore the different mechanisms, regulations and processes in place to fund and reimburse inpatient drugs in England, Germany and France and subsequently to discuss and compare the characteristics and the associated decision-making of the systems which govern the reimbursement of inpatient drugs based on formal and informal accountability criteria.

The main research question resulting from this objective is:

How acceptable are the governance elements of regulatory frameworks concerning reimbursement and funding regulations, processes and decisions with respect to inpatient medicines in England (UK), Germany and France?

This research question is divided into five sub questions:

RQ 1: *What kind of reimbursement mechanisms and funding measures are applied to allow for the provision of drugs in hospitals?*

RQ 2: *In how far the applied funding measures and reimbursement mechanisms are influenced by particular priorities, social beliefs and economic ambitions and thus impact the availability of drugs to patients in need and the stipulated funding of drugs in the market?*

RQ 3: *Of what quality regulatory measures and decision outcomes with respect to formal and informal accountability criteria are concerning the funding and reimbursement of inpatient drugs?*

RQ 4: *In how far do regulatory systems and decisions in England, Germany and France differ with respect to their institutional design (clarity of roles and objectives, accountability) and regulatory processes (transparency, participation, predictability)?*

RQ 5: *How can the technical and regulatory differences be interpreted as ways of affecting the uptake of drugs in clinical practice?*

2.2 Study Design

For this study an explorative research design was adopted. The explorative study design was chosen in view of the limited knowledge and information available. An initial investigation of contemporary literature did not reveal publications in the area of inpatient drug reimbursement

regulations and processes in the context of activity-based remuneration. Hence, the study has to be seen as explorative and cannot fall back in a body of existing knowledge. In this circumstance the design of the study needed to be flexible to be able to examine a complex set of problems and to “uncover the boundaries of the environment in which the problems, opportunities or situations of interest are likely to reside and to uncover the salient variables that may be found there and which are relevant to the research project” (Webb 1992).

The study is based on a desk research which included a semi-structured review of “white” and “gray” literature, (i.e. official documents and other literature) and semi-structured interviews with 14 respondents. The review of pharmaceutical policies and hospital remuneration systems encompassed scientific journals, legal and regulative documents and guidelines.

For the review of the “white” literature the electronic databases MEDLINE, SpringerLink, ScienceDirect, SagePub and Wiley InterScience were searched. Further searches were performed by means of the search engine “Google scholar”. Key terms that were used included:

- Diagnosis-related-groups + drugs [or] pharmaceuticals
- Reimbursement + inpatient drugs
- G-DRG [or] GHM [or] GHS [or] HRG
- Payment-by-result + hospital drugs
- High-cost-drugs + hospital
- Hospital reimbursement [or] hospital remuneration + drugs
- Activity-based-costing [or] –funding [or] –reimbursement [or] -remuneration
- History + hospital funding [or] -financing
- Hospital + drugs

The sources identified were reviewed for their relevance and date of publication. Priority was given to studies and articles published in or after the year 2007 and preferably authored by national experts with a certain focal point.

The gray literature concerns national guidelines, laws and technical documents published by ministries, sponsors or technical institutions and has been examined by directly accessing their associated websites:

- <http://www.g-drg.de/cms/>
- <http://www.atih.sante.fr/>
- <http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Managingyourorganisation/Financeandplanning/NHSFinancialReforms/index.htm>
- <http://www.aok.de/bundesweit/>
- <http://www.ic.nhs.uk/>
- <http://www.audit-commission.gov.uk/Pages/default.aspx>
- <http://www.sante-sports.gouv.fr/>

Particular respect was paid to deadlines, processes and calculation methods. The study of this grey literature is demarked by the relevance of the document regarding the report of regulatory requirements and temporal processes as well as by the date of publication (preferably published no longer ago than 2007). Besides, all general technical documents regulating the systematic of hospital funding as well as all cost-price-lists and price lists for alternative and supplementary funding from 2005 on, have been reviewed.

Because of the research was following an iterative approach, not only the framework was determining the topic list for the interviews in terms of explicitly incorporating questions concerning the identified criteria of formal and informal accountability but also the desk research. Several questions have not been able to be answered adequately because of the research's objectives focusing on the acceptability of regulatory frameworks regarding the funding and reimbursement of inpatient drugs. That means, often the literature review revealed stipulated regulatory measures and academic discussions on particular issues concerning patient-classification and inpatient reimbursement and provided a descriptive delineation of governance elements, however, since part of this research was to evaluate the quality and acceptability of regulatory frameworks, the information was not suitable for the purpose of analyzing regulations, processes and decisions on notions of formal and informal accountability. Hence, the repetitive ascertainment of individual perceptions from different perspectives was essential to generate results with a comprehensive explanatory power.

Respondents for the interviews have been chosen based on their expertise with the inpatient drug reimbursement systems in the examined countries. In the recruitment process it was aimed to find experts such as directors in charge of hospital pharmacies belonging to the group of maximum providers or research-based university hospitals (n=3). Furthermore, experts from regional health authorities (RHA) or trusts were asked to participate in the study (n=2). Furthermore, technical institutions charged with the development and maintenance of the different activity-based funding systems were approached (n=3). If necessary further information concerning e.g. priorities or political intentions were able to be obtained by conducting interviews with representatives from ministries or sponsors (n=3). Finally, representatives from the pharmaceutical industry were asked about their perceptions, experiences and possible problems with the applied mechanisms and processes of inpatient-drug remuneration in the context of activity-based hospital funding (n=3). The interviews explored perceptions, views, and concerns with regard to the remuneration of inpatient drugs. All respondents were able to generate their individual concerns and the interview guide allowed for the discussion of emerging issues in the process of conducting the interviews. The interviewees were emphatically reminded to focus upon their area of expertise and as the case may be exclude "speculations" about questions which they are not familiar with.

Respondent #	Country	Field of expertise/ occupation	Date of Interview
1	Germany	Pharmaceutical Industry	June 24, 2009
2	Germany	Hospital Pharmacy	July 1, 2009
3	Germany	InEK	September 11, 2009
4	Germany	Ministry of Health	June 2, 2009
5	Germany	Statutory Health Insurance Association	June 29, 2009
6	France	Regional Hospital Agency	August 4, 2009
7	France	Pharmaceutical Industry	September 9, 2009
8	France	Ministry of Health / ATIH	July 9, 2009
9	France	Hospital Pharmacy	August 8, 2009
10	England (UK)	NHS PCT	August 10, 2009
11	England (UK)	NHS IC	September 13, 2009
12	England (UK)	Pharmaceutical Industry	July 1, 2009
13	England (UK)	Audit Commission	July 3, 2009
14	England (UK)	Hospital Pharmacy	June 22, 2009

Table 2.2.1: List of interviewed Country-Experts

The in-depth semi-structured interviews were conducted between June and September 2009 by the same researcher. The approximate 45' min telephone interviews were digitally recorded and transcribed verbatim.

2.3 Data Analysis

A preliminary analysis of the information provided was performed after each interview in order to identify issues which required further exploration (Pope et al. 2006). In the continuous analysis the collected data was organized into "all-inclusive and mutually exclusive" coding categories (Raymond 1992), following an inductive approach. Subsequently, the coded units were labeled as specific concepts and classified or rather grouped within each criterion (ibid. Table 2.3) into a particular category (A-E) applied to indicate supporting and constraining features and characteristics of the different hospital remuneration, based on Stern and Holder's framework to assess the quality of regulation. The interpretative and theoretical validity of the analysis is ensured through the use of the constant comparative method (Boeije 2002). In order to manage the data Microsoft's Excel 2007 was used.

Based on the analysis of both interviews and literature it was possible to assess the strength and weaknesses with regard to formal and informal accountability notions concerning regulations and decision-making processes in inpatient drug reimbursement systems. In terms of the most favorable

conditions a ranking of A was given. An A-ranking would basically imply a best-practice example. An E-ranking in contrast implies that the level's specific regulatory setting is highly unfavorable and an uncertain regulatory situation exists. Rankings B, C and D are given for regressively less favorable regulatory settings. The categorizations used should be taken as indicative rather than exact, and represent the 'best' subjective judgment possible given the information available from surveys conducted with a similar focal point³. The definition of each category of the five criteria is set out in the table below:

Aspects	Definition of the most favorable (Rank A) and the most constraining (Rank E) regulatory setting
Clarity of Roles and Objectives	<i>Rank A:</i> Roles, responsibilities and decision-making capabilities are well-articulated and clearly separated from each other. Objectives, goals and priorities are clearly stated and publicly accessible as well as assignable to a particular stakeholder
	<i>Rank B:</i> Roles, responsibilities and decision-making capabilities are well-articulated and clearly separated from each other. Objectives, goals and priorities are clearly stated and publicly accessible as well as assignable to a particular stakeholder but doubts exist as to its effectiveness in practice
	<i>Rank C:</i> Legal provisions exist on regulation, but neither these nor established practice introduce a real division between regulation and government/sponsor or eliminate significant ambiguities
	<i>Rank D:</i> There is no primary law, but established practice recognizes a separate regulatory function in some form
	<i>Rank E:</i> No separation or specification of regulatory stakeholders is apparent. Decision-making responsibilities and capabilities as well as priorities and objectives are not regulated explicitly nor are they disclosed
Accountability	<i>Rank A:</i> There is full accountability in terms of reasoning the decision-making and appeals, including a specific legal right to readdress disagreements.
	<i>Rank B:</i> The specified means of redress are generally acceptable and the regulator is accountable for its actions in a reasonable way, but the arrangements fall short of a fully effective degree of accountability
	<i>Rank C:</i> The relevant law provides for specific means of redress for aggrieved parties, but the degree of accountability to other bodies is either inadequate or excessive
	<i>Rank D:</i> Accountability is limited to the general legal rights of an aggrieved party to argue that a decision is contrary to the relevant law
	<i>Rank E:</i> There are no formal mechanisms of accountability, no need to reason the decision-making nor an opportunity to address disagreements

³ **E.g.:** Blum et al. 2009. Anspruch und Realität von Budgetverhandlungen zur Umsetzung medizintechnischer Innovationen Gutachten des Deutschen Krankenhausinstituts (DKI) im Auftrag des Bundesverbandes Medizintechnologie (BVMed). Düsseldorf [www.dki.de].

Dr. Wilke GmbH. 2007. Studie: Stellenwert der Innovationsentgelte für Deutsche Krankenhäuser. München.

BMG. 2007. Umfrage des BMG zur DRG-Einführung [http://www.uni-duesseldorf.de/AWMF/drg/bmg-umfr.htm].

Audit Commission. 2005. Early Lessons from Payment by Results.

Audit Commission. 2008. The right result? Payment by Results 2003-07.

Participation	<i>Rank A:</i> A comprehensive process of formal consultation (including public hearings and publication of and comment on consultation responses) involving all concerned stakeholders is exercised before decisions are made.
	<i>Rank B:</i> An acceptable process of consultation is followed, but it in some respects falls short of public hearings, publication of consultation responses and taking account of views
	<i>Rank C:</i> Formal consultation is limited to submission of views
	<i>Rank D:</i> No significant formal consultation takes place
	<i>Rank E:</i> No consultation with concerned stakeholders takes place
Transparency	<i>Rank A:</i> All regulatory documents are available to the public, the regulator publishes major decisions as well as the reasoning behind major decisions, and discloses criteria and decision-making processes. Deadlines and requirements are clearly stated and compliable in a reasonable time.
	<i>Rank B:</i> The regulator publishes the reasoning behind major decisions
	<i>Rank C:</i> Major documents are available as above, and the regulator also publishes major decisions
	<i>Rank D:</i> Major regulatory documents, such as laws, licenses or concession agreements are in the public domain
	<i>Rank E:</i> There is no significant public information available regarding regulatory instruments, decisions, priorities or decision-making processes
Predictability	<i>Rank A:</i> The “rules of the game” are not changed arbitrarily and allow for assured planning security
	<i>Rank B:</i> The “rules of the game” cannot be changed without changes in primary law, and key regulatory instruments or documents cannot be changed without undergoing appropriate processes
	<i>Rank C:</i> The “rules of the game” can be changed without changes in primary law, but key regulatory instruments or documents cannot be changed without undergoing appropriate processes
	<i>Rank D:</i> The legal framework for regulation cannot readily be changed, but changes to regulatory instruments or documents can be made relatively easily
	<i>Rank E:</i> There are no explicit “rules of the game” the decision-making is arbitrarily and differs along individual cases. A manufacturer does not have any planning security. Decision outcomes and processes are uncertain

Table 2.3.1: Ranking definitions of appraisal criteria

2.4 Scope and Limitations

This study can be seen as the first one which addresses the issue of inpatient drug remuneration regulations and processes in a political context and from an international comparative point of view. It was carried out with the initial “aim [...] to point out the best [...] among the alternatives that are being studied” (Routio 2007). However, “[...] comparative analysis is [also] expected to provide grounds for the planning of improvements to existing circumstances or products.”

With respect to the different health care settings between and even within the examined countries the study provides decision-makers with abstracted and qualified information or rather information which is – as it was examined – merely applicable in a direct way to these settings or regions where it was conducted. Thus, a direct transfer of the findings, implications and recommendations to another health care setting or region than the one where the information was obtained from might be biased and lead to different outcomes than concluded from the data. Furthermore, the multitude of individual settings as well as limited ‘research capacities’ such as financial constraints and the involvement of only one researcher did not allow for a final quantitative-based validation of all obtained insights and results. Moreover, the illustrated insights represent “merely” a snapshot of the most recent past until the present. However, numerous legal changes regarding hospital funding and the regulation of inpatient drugs have been already initiated and some will likely to be implemented in the near future. Consequently the research entails an initial exploration of the subject which suggests that further research is not only needed but also logical.

With regard to the analytical framework of Stern and Holder (1999) it has to be noticed that an inpatient reimbursement system can be evaluated validly just from a rather limited perspective, i.e. from a “political” or rather “social science based” one. To gain a holistic idea about the quality of inpatient reimbursement in the different countries a detailed indication-specific analysis of all medical and economic parameters influencing the decision- making and determining the entire system would be of necessity. Thus, the framework provides a good base to obtain a general overview and to generally assess inpatient reimbursement systems but e.g. product specific decisions require more detailed insights and examinations.

2.5 Structure of the Thesis

The introductory chapter provides an overview of the change in financing hospitals and inpatient activities from open-ended budgets based on the length of stay to prospective hospital budgets based on case-mix. Moreover, an insight is given to recently published literature dealing with related topics research within this paper.

Chapter 2 entails the theoretical approach applied in order to analyze and assess the quality of regulation of inpatient drug reimbursement systems and the research objective and questions the study was following. Furthermore the used methodology was introduced in terms of data collection and analyses.

In Chapter 3 the different established activity-based hospital remuneration systems in Germany, England and France will be illustrated very shortly before focusing upon the reimbursement of inpatient-drugs. Thereby regulations and processes concerning innovation-remunerations and additional or rather supplementary remunerations of high-cost-drugs will be separately analyzed.

Based on these findings, Chapter 4 will be a comparative analysis of the different inpatient

remuneration systems using 5 criteria of formal and informal accountability in order to examine and evaluate the quality of regulation and decision-making processes.

Finally, in Chapter 5 learning's from the research and implications will be discussed before drawing a final conclusion.

3. FACTUAL INFORMATION ON PATIENT-CLASSIFICATION-SYSTEMS AND ALTERNATIVE FUNDING MEASURES

3.1 Introducing Activity based hospital reimbursement

Over the past 20 years, most European countries introduced activity-based hospital reimbursement using patient-classification-systems like diagnosis-related groups. By means of patient classification systems it is in general attempted to relate the type of hospital cases to the resources used by the hospital (Muldoon et al. 1998). Therefore treatment cases are usually categorized on a) clinical data like diagnoses and procedures; b) demographic data like age and gender and; c) data documenting the resource consumption like costs and length of stay (Canadian Institute for Health Information 2004). The initial approach of constructing clinically meaningful and economically comparable groups of clinical pictures in patients was firstly undertaken by Robert Fetter and colleagues from the Yale University on behalf of the USA Medicare system. In 1983 the Health Care Financing Administration (HCFA) was introduced under the US Medicare system as virtually the first patient classification system for the purpose of determining hospital payments. Meanwhile, most of the European countries have successfully adapted and fully implemented their individual case-payment-system for hospitals. Although each country claims the uniqueness of its system (and in fact the HCFA-DRG has been undergone a substantial modification and re-design) the methods used to classify patients and the underlying goals of prospective payment systems using patient classification systems are actually based to some extent on the initial approach of Fetter (Schreyoegg et al. 2006; Fischer 2007; Reid&Sutch 2008). In the original concept of DRGs three different objectives were labeled: 1) reducing costs; 2) increasing benefits and 3) increasing quality of health care (Fetter 1991). There were tendencies to follow merely the first two goals without taking the quality goal into account appropriately (Fetter 1991).

France was the first country in Europe that adopted and modified the HCFA system in 1986. As a result the so called GHM (Groupes Homogenes de Malades) were designed. GHMs were further developed into the activity-based- PPS system (prospective payment system) introduced in 2004 and advanced by so called GHSs (Groupes Homogenes de Sejours) used for the reimbursement of inpatient activities.

In England the Department of Health published “Reforming NHS Financial Flows – Introducing payment by result” in October 2002 based on deliberations already occurring since the early 1990s. This document introduced a new funding system for the work done by the NHS in England (DH 2002). Individually negotiated block contracts were replaced with a different reimbursement scheme. Now, cost and volume payments for each procedure a hospital provided were linked to the actual labor (“activity”) done. In order to classify health care activity in a way that accounts for the complexity and mix of cases, Health Care Resource Groups (HRG) were developed based on the US HCFA system.

The German patient classification system was adopted from Australia. The Australian patient classification system in its turn already entailed modifications of the original HCFA system. The SHI-health reform act in 2000 tied in with the introduction of prospective and activity-based lump sums and supplementary payments. The reform aimed towards a reimbursement of all inpatient treatments based on German-Diagnosis-Related Groups (G-DRGs).

The functioning and the quality of the design of patient-classification systems but also the entire rest of hospital funding issues is significantly depended from particular institutions and authorities which are capable of determining directions, stipulating regulations and making decisions. The scope of power, competencies and responsibilities may thereby differ and often relates to the institutional level in which authorities are anchored. Furthermore, each authority follows its own goals depending on its duty and interests (ibid. Appendix "A1"). This might impact the funding of drugs.

In order to understand the impact patient-classification systems have on the reimbursement of medicines in the hospital practice, the following section will deal with the systematic of patient-classification and the "post-production-phase" which is attended by the way patient-classification systems are maintained and updated. In the further course of chapter 3, also measures applied to reimburse and fund new or innovative drugs ought to be described before turning to the examination of alternative funding measures. Because of individual measures and regulation in place as well as decision-making processes differ between the examined countries information on the different domains of funding will be provided sub-structured according to one specific country.

The structure chapter 3 will follow is thus:

- a) Systematic of Patient-Classification-Systems: Regular funding and reimbursement measures based on patient-classification systems
- b) Innovation Remuneration and Supplementary Reimbursement
 - a. Innovation remuneration
 - i. England
 - ii. Germany
 - iii. France
 - b. Regular supplementary reimbursement
 - i. England
 - ii. Germany
 - iii. France

Although the thesis problem focus is to analyze the quality of inpatient reimbursement regulations and processes in England, Germany and France the factual information on patient-classification systems and alternative funding measures provided in chapter 3 is considered essential to

accomplish the analysis. As a matter of fact, dealing with formal and informal accountability in reimbursing and funding hospital (drugs) requires at least a general understanding of funding measures applied and decision-processes taking place.

3.2 Systematic of Patient-Classification-Systems – Drug-Cost-Fractions as Part of Activity-Based Hospital Budgets

Innovative progress, shifting demographic structures, health care reform attempts and permanent efforts to contain costs require law-makers and regulative authorities to react perpetually dynamic and flexible on changing activities and services, prices and costs occurring in single hospitals. In order to be able to determine individual and up-dated hospital budgets based on actual hospital activities and their costs the update of patient classification systems and the calculation of DRG-prices is an annually recurrent process. Simplified the updating- and price-setting process could be summarized by “1 year data collection, 1 year calculation and in the third year the collected cost data will be displayed in prices” (Respondent 1).

In all countries the way updates and re-assessments of patient-classification-systems are organized causes a post-production phase or rather a time-gap of 2-3 years. As prices are adjusted retroactively new drugs that are entering the hospital are not mapped in the activity-based hospital budget and will face difficulties to be financed no matter how innovative they really are (Respondents 1; 3; 4; 7), as pictured in the figure below:

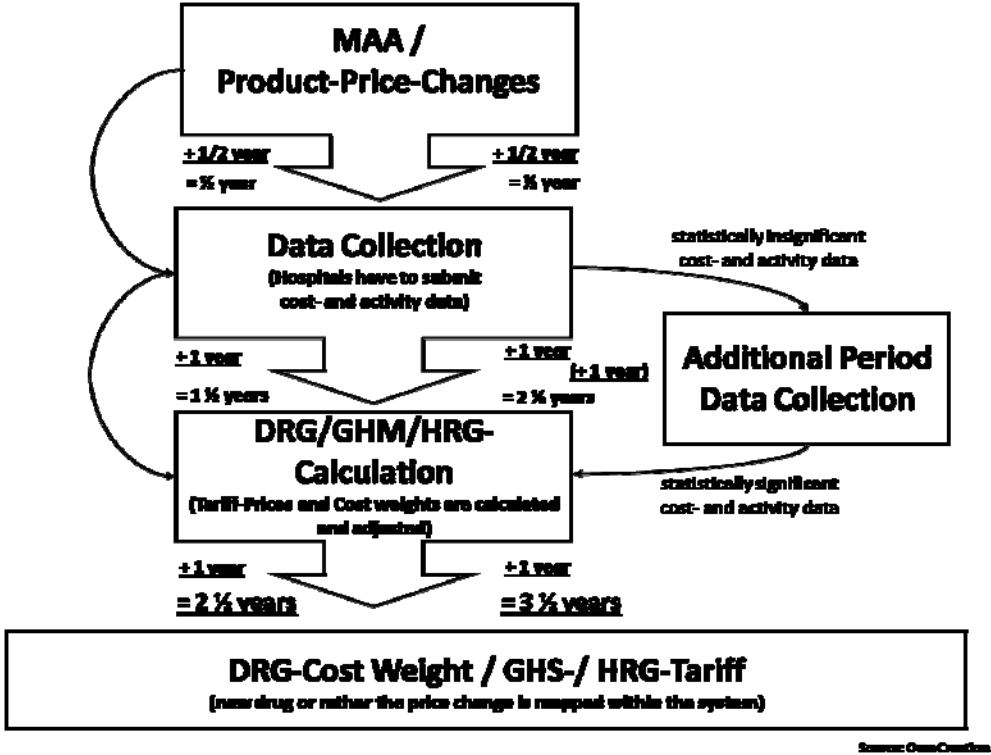


Figure 3.2-1: Systematic of Mapping new Inpatient-Activities in Patient-Classification-Systems

For the trace of a better understanding the following self-constructed example should be cited:

Assuming that a new drug was entering hospitals in July 2008 (right after the EMEA’s marketing approval for the product) and the hospital had sufficient funding sources from its budget to actual use the drug; all the cost data, the number of treatment cases, the procedure code and other data have to be submitted for the reference cost collection 2009 to the institution in charge of calculating tariffs (ATIH, InEK, NHS IC). No matter when the reference cost collections are taking place and for how long they are conducted in the following year (2010) the institutions will be recalculating the prices of DRGs/GHSs/HRGs incorporating the submitted cost data. On the condition that an adequate amount of sufficient cost data was provided by hospitals, which allow for statistical reliable and valid estimations, the new drug’s price will be displayed in one of the calculated DRGs/HRGs/GHSs. In case the delivered data was not sufficient or rather an inadequate amount of case-based data was submitted calculations will be delayed until more data can be provided, hence, until the drug was used more often in the hospital practice (as the case may be after one more year in the reference cost collection 2010). As from the beginning of the new budget year in 2011 (or 2012) the tariffs would include the average costs of the newly introduced drug which would be eventually covered within the system after 2 ½ years (3 ½ years).

The appendix provides an additional document dealing with the opportunity for unscheduled updates and reassessments including an outline of participation potentials (ibid. “A3”). How the calculation and update processes are exercised in each of the three countries will be marked out very shortly below. The figure below provides a general overview of the patient-classification-system used and steps practiced in each of the three countries in order to define Reimbursement rates:

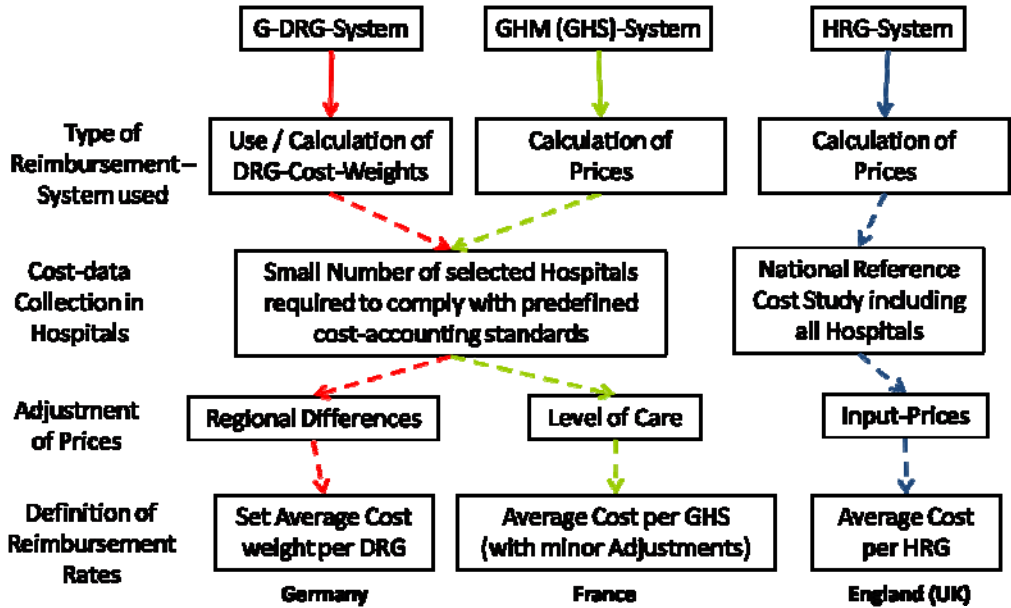


Figure 3.2-2: Country-Overview of Reimbursement Rate Definition

Although the countries' methodologies of ascertain updated cost-prices for case groups (G-DRG, HRG, GHS)⁴ differs significantly in its application, there is a common concept which can be described in three general stages: 1) Data collection 2) Cost-Price-Calculation 3) Definition of case-group prices. (More information on the three steps can be found in Appendix "A2").

The definition of case-group prices is often explained just sporadically (usually based on single examples) and influenced by certain priorities such as the attempt to increase the hospital's level of reservation when administering drugs in terms of cost-containment efforts. Moreover, e.g., in France "it's a nightmare to split DRGs and the other nightmare is to increase the hospital budget. The best thing is if a drug can be included in an existing DRG price" (Respondent 8). Thus, even though knowing the priorities makes decisions more predictable the outcomes may be less favorable.

In England most of adjustments are applied more or less intuitively without a comprehensive reasoning of how particular values were estimated (Respondent 12 + 13 +14). In fact there is a final document explaining all accomplished changes, but due to the fact that changes are often based on the opinion of a small group of experts transparency is lacking. This also means that issues like HRG-splits or the increase/decrease of the monetary value of an HRG can be ascribed logically; however, no official reasoning is done. This in turn constrains the possibility to challenge made decisions legally in a well substantiated and effective way. Furthermore, it appears to be impossible to clearly appoint stakeholders who will finally make decisions or to comprehend the reasoning of the decision-making on e.g. case group splits or rather the assignment of cost-parameters to particular case-groups. Thus, there is a clear lack of accountability, transparency necessary in order to challenge decisions or to engage in a public discussion (Respondent 10). The way HRG and GHS budgets currently are derived is broadly perceived as being very difficult due to its technical complexity. Even though the "Department of Health would say it's a great system which is very transparent [...] it is almost impossible to get to the bottom of any decision-making process" (Respondent 13).

In contrast to France and England, Germany is applying cost weights "which define a relationship between treatment episodes according to the intensity of resources used" (Schreyoegg et al. 2006) in order to meet regional differences. Cost weights have the advantage that merely the price of the DRG with the cost weight of "1" has to be set or negotiated, what makes the system generally more predictable. All other DRG prices may be derived automatically by multiplying the DRG cost weight attached to each DRG with the price set for the DRG with the cost weight of "1" (Ankjær-Jensen et al. 2006). Thereby prices for a single product will be less biased and it is more difficult to influence them according to certain priorities such as the undervaluation of particular case groups. However, the indicative DRG with the cost weight of 1, the so called state-wide base rate, may differ among the different federal states (Länder) in Germany. Base-rates are matter of negotiation among the state hospital associations and statutory sickness funds. The state-wide base-rates in 2009 were ranging from €2775.00 in Sachsen-Anhalt to €3008.08 in Rheinland-Pfalz (cf. AOK 2009).

⁴ i.e. the way of how cost data is collected and reimbursement rates are calculated

Transparency and accountability requirements are tried to be met by publishing 'migration-table'⁵ showing all DRG-splits, DRG consolidations, etc. in order to be able to retrace all changes. A semi-public reasoning is attempted with the publication of an annual 'final report'⁶. The provision of a holistic understanding, however, fails to appear and is not wanted either as it would enable the opportunity for lawsuits (Respondent 1 + 3). In fact the decision-making process itself as well as the publication of the InEK's reasoning with regard to the made decisions appears to be a "two-edged sword". None of the interviewed experts was evaluating the decision-making process as being very transparent. Yet, hospital- and sickness fund associations seem to agree strongly with that way of decision-making. Merely, the Association of Research-based Pharmaceutical Companies was publishing in 2006 a position paper which argued for more transparency in the decision-making process and a detailed reasoning with regard to the made decisions (vfa 2006). However, there are influential voices within the industry itself that are highly in favor of how decisions are made. The interviewed industry expert emphasized the "extreme pharma-amiability" of the G-DRG-system and noted that "increased possibilities for law-suits would not make the system more favorable [for a pharmaceutical manufacturer] but prolong the decision-making processes tremendously".

Overall, the price-setting procedure in all countries is influenced by certain political priorities and cost-considerations that influence technical implementations to some degree. Subsequently, accountability and transparency issues arise due to the absence of a comprehensive reasoning how decisions were made as these ones would provide the opportunity for a broad societal discourse.

Summing up the interviewed stakeholders' perceptions with regard to activity-based hospital funding, it turned out that even though there are problems and further challenges, no one was considering another hospital funding system as being a serious alternative. In fact, "the basic idea underlying activity-based funding is quite reasonable and the systems seem to work in each country" where they have been established (Respondent 14). Yet, the systematically-caused delay in updating case-group prices and mapping new medical parameters as part of the existing patient-classification requires additional measures in order to provide patients in need with the opportunity to be treated sufficiently. These measures will be delineated more concrete in the next sections.

3.3 Innovation Remuneration and Supplementary Reimbursement as Necessary Components of Inpatient-Drug Funding – Coping with System-Imminent Weaknesses of Patient-Classification

Most drugs used in inpatient facilities are part of prospectively determined hospital budgets based on case-mix. Their costs, which are accruing during a treatment episode, are incorporated into the particular case-group-prices derived from the above described process of calculating cost-weights,

⁵ http://www.g-drg.de/cms/index.php/inek_site_de/G-DRG-System_2009/Fallpauschalen-Katalog/Migrationstabelle

⁶ http://www.g-drg.de/cms/index.php/inek_site_de/G-DRG-System_2009/Abschlussbericht_zur>Weiterentwicklung_des_G-DRG-Systems_und_Report-Browser

base rates and prices. However, due to the way of how patient classification-systems are organized, maintained and designed it is difficult to include each inpatient activity in a case-group that allows for the reimbursement of hospitals to stipulated monetary conditions.

Thereby, the first major weakness of patient-classification-systems is the above delineated post-production phase. This temporary offset may impede the immediate uptake of new treatment options or rather drugs, after they have been approved by the EMEA. This situation applies for two scenarios: 1) the price of a new treatment option exceeds the determined prices of the standard of care or 2) the treatment option is simply so new that it has not been medically mapped within the case-group.

The second weakness concerns drugs, which are already established in the clinical practice but difficult to map in a case-group due to the fact that they would cause a price fluctuation of a particular case-group or are rather used irregularly and not predictably enough to calculate their costs into case-group-prices.

Mainly in order to cope with the weaknesses of patient-classification-systems two remuneration components have been established. These are on the one hand “supplementary innovation remunerations”, which are thought to compensate for the problems resulting from the post-production-phase and on the other hand “regular supplementary reimbursement” aimed to support the administration of in particular high-cost-drugs which are not easily to map in case-groups.

Although, both supplementary funding measures are comparable in the examined countries, granting processes as well as regulatory settings and financial decisions differ significantly. This often results in diverging decision-outcomes with respect to the time a drug will be able to be administered in the clinical practice to an assured funding. Thereby, several components, such as objectives, transparency, accountability and the ability of all involved stakeholders to participate in decision-making processes impacts decision outcomes. How these decision outcomes look like in each of the examined countries and how they relate to these components will be examined for both, supplementary innovation remuneration and regular supplementary reimbursement in the following pages.

3.3.1 “Supplementary Innovation Remuneration” – Vanquishing the Post-Production-Phase

The way patient-classification-systems are updated causes difficulties to administer especially innovative high-cost drugs. The administration of these kinds of drugs is often retrained because often cost-prices of case groups do not cover the incremental costs of new and more expensive medicines. Due to that critical background legislators in all three of the examined countries decided to introduce a temporary limited remuneration for new and innovative products in order to assure their supply for patients in need. However, the applied instruments are often influenced by cost-containment considerations and therefore do not guarantee an unlimited access to new and expensive products.

How the single instruments are designed and applied in each of the three countries as well as the priorities they are influenced by will be scrutinized in the following section.

3.3.1.1 Germany: “New Diagnostic and Therapeutic Procedures” (NUB)

In Germany, the funding of costly new drugs is being regulated in the Hospital Remuneration Law (KHEntgG). In general innovative drugs that are not mapped in a DRG may be eligible for supplementary funding – the so called “new diagnostic and therapeutic procedures” (NUB – ‘Neue Untersuchungs- und Behandlungsmethoden’). In particular §6 of the KHEntgG (2) contains of all necessary information concerning application deadlines, negotiations and requirements in order to receive remuneration for a new and innovative drug⁷.

In practice, each hospital that wants to use a new product, that is not funded sufficiently, has to apply in a first step individually for a product-specific NUB-status assigned by the InEK (KHEntgG §6 (2)). The InEK is reviewing and evaluating all the individual applications submitted by single hospitals for the purpose of assigning a commonly valid NUB-status to the new product. By exercising this approach and not allowing for only one mutual application from all hospitals the InEK aims to develop a more differentiated picture about the new drug’s nature with regard to additional costs, the expected number of patients treated in the future and the kind of treatment (Deutsche Krankenhaus Gesellschaft 2005, 2008). The gathered information helps to ascertain a more data-based NUB-status and supports the placement of the new drug in the DRG-system to a later point in time (Respondent 3). There are in total 4 NUB-states⁸ stipulated in the “procedure vertexes”⁹, a legally binding document

⁷ **§6 KHEntgG (2)** “Für die Vergütung neuer Untersuchungs- und Behandlungsmethoden, die mit den Fallpauschalen und Zusatzentgelten nach § 7 Satz 1 Nr. 1 und 2 noch nicht sachgerecht vergütet werden können und die nicht gemäß § 137c des Fünften Buches Sozialgesetzbuch von der Finanzierung ausgeschlossen worden sind, sollen die Vertragsparteien nach § 11 erstmals für das Kalenderjahr 2005 **zeitlich befristete, fallbezogene Entgelte oder Zusatzentgelte außerhalb des Erlösbudgets** nach § 4 Abs. 2 und der Erlössumme nach Absatz 3 vereinbaren. Die **Entgelte sind sachgerecht zu kalkulieren**; die Empfehlungen nach § 9 Abs. 1 Satz 1 Nr. 4 sind zu beachten. **Vor der Vereinbarung einer gesonderten Vergütung hat das Krankenhaus bis spätestens zum 31. Oktober von den Vertragsparteien** nach § 9 eine Information einzuholen, **ob die neue Methode mit den bereits vereinbarten Fallpauschalen und Zusatzentgelten sachgerecht abgerechnet werden kann**. Die Vertragsparteien nach § 11 haben die Information bei ihrer Vereinbarung zu berücksichtigen. Liegt bei fristgerecht erfolgter Anfrage nach Satz 3 bis zur Budgetvereinbarung für das Krankenhaus eine Information nicht vor, kann die Vereinbarung ohne diese Information geschlossen werden; dies gilt nicht, wenn die Budgetvereinbarung vor dem 1. Januar geschlossen wird. Die Entgelte sollen möglichst frühzeitig, auch unabhängig von der Vereinbarung des Erlösbudgets, nach § 4 vereinbart werden. **Wird ein Entgelt vereinbart, melden die an der Vereinbarung beteiligten gesetzlichen Krankenkassen Art und Höhe des Entgelts an die Vertragsparteien nach § 9; dabei haben sie auch die der Vereinbarung zu Grunde liegenden Kalkulationsunterlagen und die vom Krankenhaus vorzulegende ausführliche Beschreibung der Methode zu übermitteln**. Die Vertragsparteien nach § 9 können eine Bewertung der Untersuchungs- und Behandlungsmethode nach § 137c des Fünften Buches Sozialgesetzbuch veranlassen; § 137c Abs. 1 Satz 1 des Fünften Buches Sozialgesetzbuch bleibt unberührt. Für das Schiedsstellenverfahren nach § 13 kann eine Stellungnahme des Gemeinsamen Bundesausschusses nach § 137c des Fünften Buches Sozialgesetzbuch eingeholt werden.“

⁸ **Status 1:** The inquired method/provision fulfills the requirements of the NUB-agreement. According §1 (1) of the NUB-agreement the stipulation of an individual hospital remuneration is admissible.

Status 2: The inquired method-provision does not fulfill the requirements of the NUB-agreement. According §1 (1) of the NUB-agreement the stipulation of an individual hospital remuneration is not admissible.

agreed on by sickness funds and hospitals. Formal requirements and procedures for the awarding of a NUB-state are stipulated in the vertexes. Depending on the awarded NUB-state the reimbursement of a drug is either eligible to be negotiated between sickness funds and hospitals or not. Thereby only NUB-state 1 theoretically allows hospitals to negotiate innovation remuneration with sickness funds without any constraints, as illustrated in the figure below. All other NUB-states either limit the possibility to negotiate additional remuneration or forbid the same. The NUB status is granted for one year. In case the new drug is not mapped in the DRG-system in the following year a new NUB has to be applied for all over again. The figure below illustrates exemplarily the general course an innovative drug that is entering the market will face until its uptake and funding are assured:

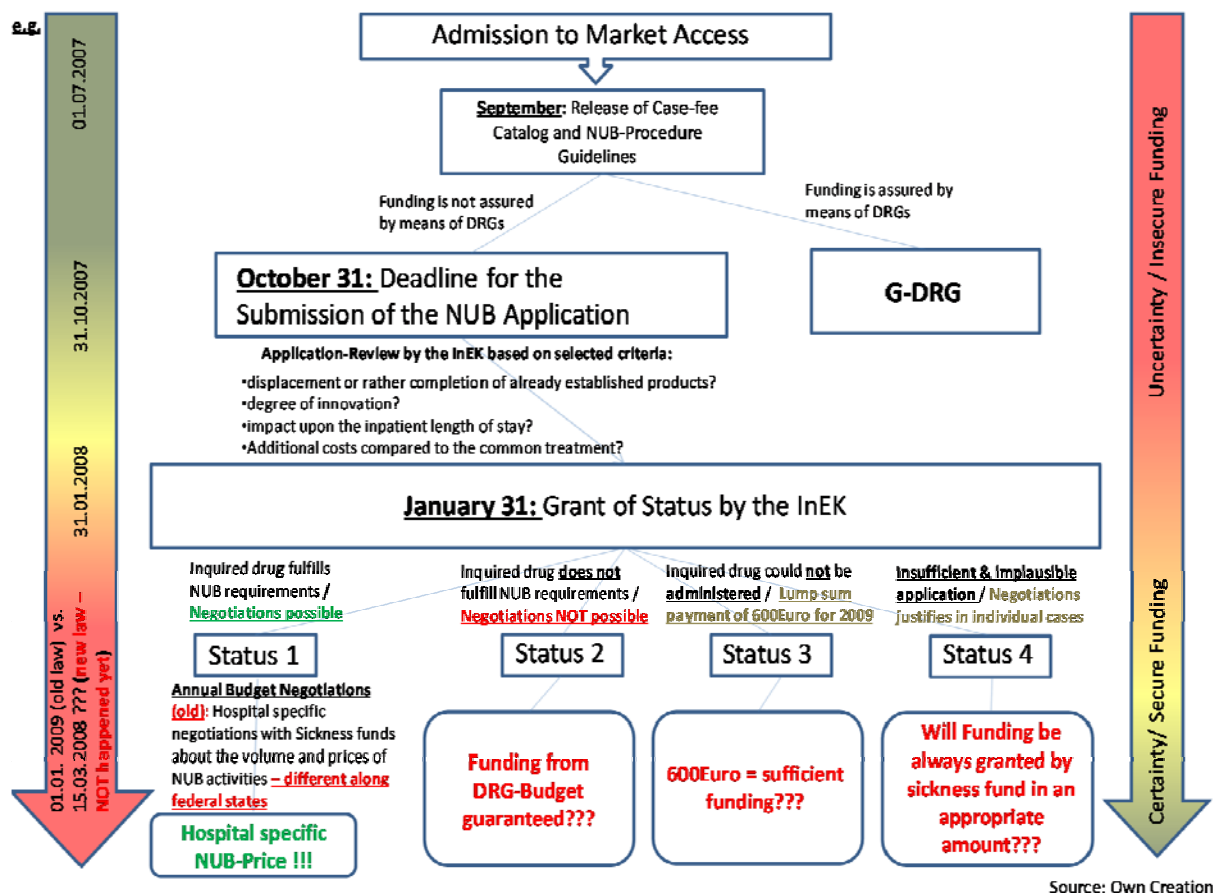


Figure 3.3-1: General Course of Innovative Drugs from MAA to Financially Assured Administration

The most essential factor in order to obtain a positive NUB status is to prove that the drug of concern really is a new and innovative product. Furthermore, the medical description of the drug, i.e.

Status 3: The inquired method/provision was not being able to be administered within the statutory terms. According §6 (2) KHentgG an agreement between the contractors can be stipulated, even though the InEK's response is not available. (Lump sum payment of 600Euro for 2009)

Status 4: The inquired method/provision was insufficiently or implausibly applied for. Hospitals are eligible to negotiate in justified individual cases individual hospital remuneration for the drug on condition that there is no budget agreement for the coming year, yet.

⁹http://www.g-drg.de/cms/index.php/inek_site_de/Neue_Untersuchungs-_und_Behandlungsmethoden_NUB/Verfahrenseckpunkte

which common treatments are displaced or rather supplemented is highly important. If the necessity of supplementary funding is not proved sufficiently the drug runs the risk of being stated by the InEK with status 4. Another decisive factor is the calculation of additional costs. In particular the costs of new drugs which displace other common and established treatments have to be deducted from the costs which arose hitherto by the old treatment for the purpose of estimating the true costs of innovation. In case it turns out that the drug is “too cheap” (Respondent 1+3) it will be hardly possible to have a NUB granted. Although the InEK’s work can be assessed as methodology driven and predictable as a whole as the application requirements show, transparency is sometimes lacking. For one because there is no such thing as a threshold which defines the range of costs the administration of a drug would have to produce in order to be eligible for a NUB-status that allows for supplementary funding. Yet, usually drugs which are less costly than 500 Euro will be considered as being system irrelevant and will have to be funded from the DRG-budget (similar statement by all German experts).

In general, the InEK turned out to be quite flexible (Respondent 1) and complaisant handling NUB-applications. Since the InEK’s duty is practicably “just” the pre-selection of new drugs based on a rather scientific and clear methodology there are hardly any possible barriers produced which would hinder an immediate uptake of an innovative drug in the clinical practice. However, the actual remuneration amount associated with the drug and the modus of accounting still have to be negotiated in the annual budget negotiations between hospitals and sickness funds as depicted in the figure below:

NUB-Remuneration Negotiations

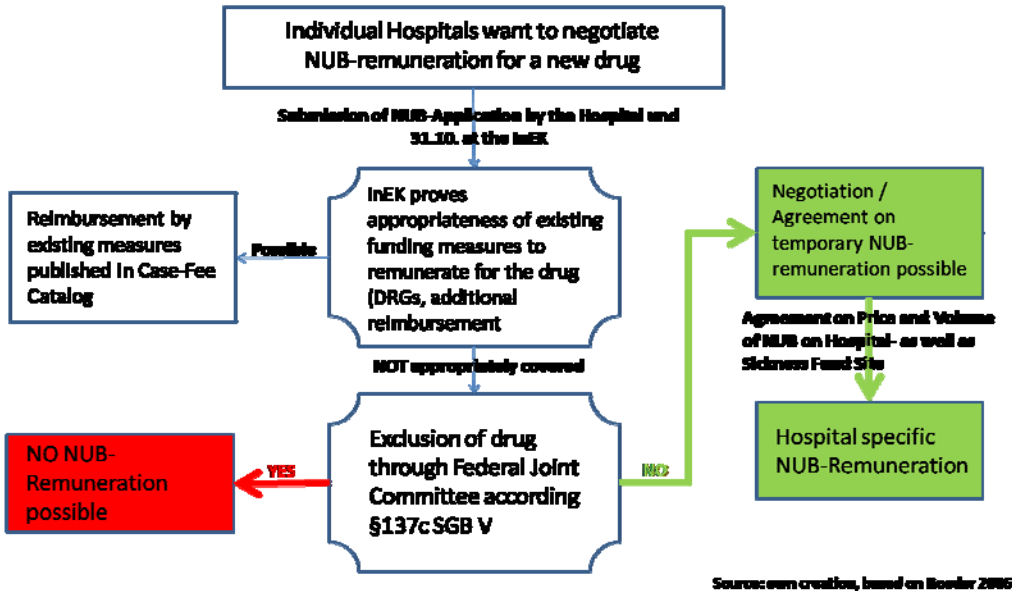


Figure 3.3-2: General Process of Negotiating Supplementary Remuneration for Innovative Drugs

In these budget negotiations hospitals have to provide detailed price and volume calculations. Yet, volume calculations were not intended by the German legislator. Consequently, the question of accountability arises, i.e. the opportunity to challenge the requirement for volume calculations legally. Sickness funds seem to have a considerable power what enables them to arbitrarily define the rules of the game without the urge of substantiating their decisions with formal law. During budget negotiations sickness funds constantly try to adjust prices downwards by means of comparative lists which base on the results of prior negotiations with other hospitals. These lists, however, are not being disclosed and thereby do not allow for a review by hospitals. The competitive advantage makes decision outcomes hard to predict. That deficit on transparency is an intentional measure used by sickness funds in order to improve their own bargaining situation, yet it disadvantages hospitals tremendously and the quality of care provided by hospitals (Respondent 1). Besides, quite often sickness funds try to refuse the remuneration of new and innovative products despite its status 1 without providing well reasoned arguments. That situation makes it difficult for hospitals to prepare strategic arguments. Hospitals are virtually excluded from the decision-making process as a participatory stakeholder and are often merely told what will be granted to what price.

Sickness funds' diverging priorities and internal regularities along the different federal states are complicating the prediction of assured funding for new drugs which obtained status 1 even more. This means for instance that in some federal states sickness funds pass all new status 1 drugs to the medical service of the umbrella association of statutory sickness funds (MDK) which is checking the drug's effectiveness and cost-effectiveness. Subsequently the remuneration is refused without the provision of official or publicly accessible reasoning. Thus, even if the assessment of the drug's cost-effectiveness and impact upon quality of life is not formally or legally intended ex-ante in order to decide about reimbursement, it nevertheless has an impact in most of the cases, even though neither the manufacturer nor the hospital have had the chance to participate in the assessment process or to examine the submitted data.

Furthermore, the budget regulations along the federal states differ from each other. Thus e.g. "hospitals in Bavaria receive the innovation remuneration additionally the regular budget, whereas other federal states include the amount of money into the hospital budget" (Respondent 2). Consequently, there is a good "chance the sickness fund will say we accept the drug as being a NUB, however, we will deduct the same amount of money from the budget for regular supplementary reimbursement [...]. There is always the possibility sickness funds might say: well, you have the new drug, which might be effective for some patients, but what have you done so far with those patients? Is it maybe a drug which substitutes another one? Then we will decrease the budget for that drug" (Respondent 2). Hence, it is not surprising that new products are prescribed more often in federal states where innovation remuneration is granted in addition to the regular budget. This situation may result in a post-code lottery for patients in need. The time-to-patient-access or to the guarantee of

assured funding is very difficult to predict and depends on arbitrary parameters such as the priorities of a single sickness fund.

To draw a conclusion, the uptake of a new and innovative drug is instantly possible after the InEK granted the drug with status 1; however the amount of remuneration will not be stipulated until an agreement on the annual budget is finally reached. Thus an immediate uptake is indirectly hindered due to funding uncertainty on the hospital site.

3.3.1.2 *England: “Pass Through’ Payments” (PTP)*

Soon after the activity-based PbR-system was implemented barriers concerning the uptake of innovation were observed (Audit Commission 2006; Green & Baird 2006). As a reaction to these barriers ‘pass through payments’ (PTP) were introduced for the purpose of promoting a more expeditious and improved patient access to new and innovative drugs and to provide commissioners with more financial flexibility. PTPs are the only funding measure which may be applied for during a financial year in order to provide better or rather more innovative than the standard care covered by the national tariff. PTP arrangements have to be agreed in advance and have to fulfill certain basic requirements specified by the Department of Health: “Coded to a relatively high volume HRG where the activity within the HRG is heterogeneous in nature and; delivered in a limited number of centers and; of disproportionate cost relative to the HRG tariff” (PbR Guidance 07/08). The criteria to define “disproportionality” in that context may be differing among the particular strategic health authorities.¹⁰

¹⁰*E.g.: The East of England HCD Commissioning Arrangements for 2009-10 takes into account the following criteria:*

- “For an individual drug that the additional/incremental cost Full Year Effect (FYE) per patient is no less than £2,000 over the existing therapy that is within tariff or local prices, and
- The Part Year Effect (PYE) of the cost pressure to any individual provider of the drugs at purchase price (including VAT where applicable) is greater than £50,000, based on the estimated number of patients put forward for this service development and
- The drug or technology is not listed in the PbR list of excluded drugs or technologies
- If a drug is not listed as excluded from PbR and is less than £2,000 FYE per patient over existing treatments but the PYE cost pressure on a single provider is anticipated to be over £100,000 for an individual drug or technology then this could be put forward through the EoE PCTs arrangements to be considered for addition to the list of drugs or technologies “suitable for consideration for PTP”
- If the total in-year drug cost pressure (other than excluded drugs and after PbR activity changes are adjusted for) on a single provider from one PCT exceeds 1% of the total income (including Market Forces Factor (MFF)) for District General Hospitals (DGH) and specialist services from that same PCT, for all new drugs and new uses for drugs in that financial year, where these are not already funded by that PCT outside PbR (non-mandatory or mandatory tariffs or local prices) e.g. as Pass Through Payments or as drugs and in HRGs excluded from PbR through Exclusions List, then further drug developments in-year could be put forward through the EoE PCTs arrangements to be considered for addition to the list of drugs or technologies “suitable for consideration for PTP”.“ <www.npc.co.uk/policy/resources/eoe_hcd.doc> *accessed July 28, 2009.*

PTPs are particularly intended to be applied for drugs that have recently been launched and for which a NICE guidance is not expected within a short timescale or new drugs that will not be subject to NICE guidance (Pate 2009).

In order to benefit from a PTP the hospital's business manager will have to submit a full business case to the Primary Care Trust (PCT) for consideration through the Area Prescribing Committee and the appropriate PCT prioritization forum (Respondent 11). Even in case of a drug's very urgent need and its consequent use in the meantime of the review and consultations a retrospective reimbursement of the drug's costs is impossible. This appears to be particularly noteworthy considering that the time to complete the review and consultation on the effectiveness, place in therapy and cost-effectiveness of the drug is expected to take at least three to four months, thus a considerable delay in the time of the drug's uptake and a virtual barrier with regard to patient access. Moreover there are 152 PCTs, thus assuming the drug is expected to be used in all of the PCTs "at least a 152 specific business cases would have to be submitted" for the application (Respondent 13). It may be positively noted that during the time of the business case assessment by PCTs there is a high potential for participation between hospitals and PCTs, whereas the business manager has the chance to argue and substantiate the hospital's demand.

Criteria which have to be considered in a business case are quite comprehensive. Most PCTs comply with their assessment and prioritization of a new drug with Buxton's and Hanney's 'payback-criteria' (Ashwell 2009/10) published in the Journal of Health Services, Policy and Research (1996), what imparts a certain scientific standard retraceable for everyone interested and a potential matter of discussion¹¹. Business cases should focus on "clinical trials [but] shouldn't shed the light on efficacy but provide the PCT with effectiveness and cost data" (Respondent 10). The chosen approach appears reasonable because of the avoidance of a doubled structure where the roles and duties of involved stakeholders become unclear. Thus, efficacy in fact does not have to be double proofed by each PCT if it was already attested by the EMEA. The problem, however, is a virtual shifting of duties from NICE to PCTs regarding the assessment of cost-effectiveness. Even though PCTs are urged in their decision-making about the granting of PTPs to take into account NICE-HTA guidelines or rather other relevant national guidelines such as the ones from the Scottish Medicines Consortium, The Cochrane Library or the National Prescribing Centre (PbR-Guidance 2009/10; Pate 2009), it remains questionable whether each of the 152 PCTs possesses the sufficient scientific know-how in order to accomplish scientifically valid cost-effectiveness results. As these guidelines may differ from each other and no uniform assessment measures are applied it becomes "patchy: the different regional groups will come to different results and will look more to cost issues than to the cost-effectiveness" (Respondent 12) what will cause a situation of 'post-code lottery' and unpredictability, without a real need to account

¹¹ These are according to their hierarchical rank and their weight of importance in the assessment process: 1) Effectiveness; 2) Burden of Condition/Disease; 3) Equity and Fairness; 4) Deliverability and timescale; 5) Level of Engagement of public and professional in demand management; 6) Acceptability; 7) Certainty and eventually 8) Fit with national standards and targets (Ashwell 2009/10; Buxton & Hanney 1996).

for the made decisions or an instance that would monitor or control decisions based on formally legal grounds. Although the potential for post-code lottery already results from the entire decentralized application procedure, it finally increases through the inclusion of affordability criteria subject to distinctive budgetary constraints which likely dominate the pivotal considerations of PCTs in the decision-making process. Also the PCTs individual priorities may impact the funding decision decisively.

Each PCT which was either granting or not granting a PTP publishes its decision. The decision-making process itself as well as the reasoning may be summarized as rather inscrutable and as pointed out decisively influenced by the PCT's individual budget and priorities. This of course will influence the price negotiations

The drug will carry its PTP status for a maximum of three years until it is included in the national tariff or the PbR-exclusion. The individual reimbursement amount for PTP-arrangements, however, will be reconsidered for each financial year taking into account changes in the tariff and other contractual changes. This eliminates a guarantee that innovative drugs will (continue to) be used in the clinical practice due to the insecure financial coverage.

To sum up, even though the PbR-system's design is principally build on reasonable concepts which comply with requirements for a target-oriented economic regulation the introduction of arbitrariness - by leaving the realization of standards and the definition of methodological approaches to single PCT's - prevents the establishment of a common and uniform quality of care. It is striking that there are plenty of documents and regularities on the national level which would virtually lead decision-makers, i.e. PCTs, very straight in deciding about the funding of innovative drugs. These build a perfect base in order set up a good level of transparency, accountability, predictability and participation. However, by allowing PCTs to individually deviate from the regulatory framework much of the quality of regulation is negated with the result of a post-code-lottery. This situation in turn characterizes lacking transparency and predictability as well as the failure in providing the ability to challenge made decisions concerning the time an innovative drug will be available to patients in need and funded assuredly.

3.3.1.3 France: "Autorisation Temporaire d'Utilisation" (ATU) and "Protocols Thérapeutiques Temporaires" (PTT)

In general, drugs will be able to be used and administered just after they have been approved and authorized for the market. Moreover, within the scope of the 'code of medical ethics' two instruments were established which allow the treatment of patients suffering rare or serious diseases with drugs still awaiting market approval with a minimum of administrative delays – the "Autorisation Temporaire d'Utilisation" (Temporary Authorization for use = ATU) and the "Protocols Thérapeutiques Temporaires" (Temporary Therapeutic Protocol = PTT). The French Agency for Sanitary Safety of Health Products (AFSSAPS) is the decision-making authority which either grants or

refuses the market approval for new drugs or drugs for which a new indication is supposed to be established. The assessments of the AFSSAPS base on pre-clinical and clinical data gathered in trials.

Autorisation Temporaire d'Utilisation (ATU)

ATUs are intended to improve the patient-access to drugs that do not benefit from a market authorization and are not used in clinical trials. ATUs are granted on an exceptional and temporary basis as they comply with three conditions: 1) the benefit/ratio of the drug has to be supposed positive 2) there is no alternative treatment available in France 3) a rare or serious pathology is treated, prevented or diagnosed (AFSSAPS 2007). In practice there are two types of ATU – the nominative and the cohort ATU.

The nominative ATU is “for drugs prescribed to an identified patient under the responsibility of the physician treating him or her” (Respondent 8). The cohort ATU in contrast concerns a group or sub-group of patients “under the condition that the company has already applied for market authorization or has engaged to apply within a fixed delay” (Respondent 8).

Nominative ATUs are applied for by a single physician to the AFSSAPS. In its assessment of the drug for which and ATU is requested, the AFSSAPS takes into account the drug’s quality, safety, and the efficacy for the indication specified in the application. However, also the absence of treatment alternatives is taken into account. The assessment is primarily based on the drug’s investigational medicinal product profile, i.e. the quality, efficacy and safety data provided by the manufacturer as well as data retrieved from listed clinical trials in process and planned in France and internationally. Thus, the decision-making process is based on very transparent criteria which allows for retracing decisions. If the application of an ATU is refused by the AFSSAPS there is the opportunity to file an appeal to the director general of the AFSSAPS and/or by litigation before a qualified administrative court within two month from the date of notification (AFSSAPS 2007).

The time frame the AFSSAPS requires to review a drug depends on the quality and quantity of available data and on the individual therapeutic urgency. In general, if a product has been reviewed by the AFSSAPS, a decision-making will take 24-48hours. In case the product has not been reviewed a delay for setting up a file and its evaluation has to be taken into account. A granted ATU holds for a maximum treatment of one year. However, in general the duration of the nominative ATU is specified on the duration of the treatment.

Cohort ATU applications can be submitted at the same time as the application for a market approval or rather before filing an application for market approval. Hence, in contrast to the nominative ATU the application for a cohort ATU is filed by the manufacturer. The AFSSAPS assessment particularly takes into account “the pharmaceutical quality, safety and efficacy of the medicinal product for the indication claimed, the draft protocol for therapeutic use and information collection, the draft summary of product characteristics, the draft patient information leaflet and labeling, the prescribing and supplying conditions as well as the absence of therapeutic alternative

available on the French market” (AFSSAPS 2007). Similar to nominative ATUs cohort ATUs are granted for the duration of 1 year. All cohort ATUs that have been granted are easily accessible¹² via the AFSSAPS web presence.

Even though reviewed and assessed by the AFSSAPS drugs which are thought to be provided within a cohort ATU inside a hospital are also subjected to the approval decision of an expert committee. The expert committee is an inter-ministerial working group that will eventually constitute a proposal for inscription on the list consisting of hospital approved drugs, yet complies in the very most cases with the AFFSSAPS assessment/recommendation.

For both of the ATUs the manufacturer has to declare to the Economic Drug Committee (CEPS) the maximum allowance he claims to charge from hospitals. In absence of the manufacturer each hospital pharmacy that is interested in buying the ATU-drug has to declare the allowance which it is asked to pay in order to be able to acquire the drug. Subsequently, all declarations will be published. The manufacturer and all hospital pharmacies will have to report the annual turnover of the drug as well as the number of units provided or received (Respondent 9). This however does not constitute a regulative intervention into the price-setting process but ought to improve accountability against the public. Even though it can be assumed that the collected data will be used to a later point in time in order to set GHS-tariffs or to prepare for price negotiations with the manufacturers.

Protocols Thérapeutiques Temporaires (PTT)

Within the frame of the contract for a proper use of new and innovative drugs and medical devices in internal medicine (decree n°2005-1023 from August 24, 2005) the opportunity to fund drugs used in an off-label practice was established. The so called PTT primarily applies to drugs which have been evaluated as being favorable on the basis of available data. That means that a lack of the drug’s availability represents a loss of opportunity in order to sufficiently treat a patient (AFSSAPS 2007 Référentiels nationaux pour un bon usage des médicaments onéreux et innovants). The full responsibility for the PTT procedure lies with the AFSSAPS, French National Authority for Health (HAS) and the National Cancer Institute (INCA). Thereby each of those bodies is in charge of a certain medicinal product (INCA=Cancer drugs, Chemotherapy; AFSSAPS=other drugs; HAS=medical devices). The procedure of how drugs are identified which are eligible for off-label use as well as the methodology to develop a protocol has been defined in a consensus of all three institutions and can be found in detail in the “Méthodologie générale d’élaboration des protocoles thérapeutiques « hors-GHS »”. Since PTTs are granted for a maximum of 4 years, without having the “certainty” of clinical trials regarding safety and efficacy not predictable unacceptable outcomes of the drug treatment for the new indication can lead to a denial of the PTT status or rather the change of the temporary treatment protocol itself.

¹² www.AFSSAPS.sante.fr

As it can be concluded, even though the implemented measures are not directly suited for drugs having a market approval and entering the clinical practice the French measures for promoting innovation are considerably beneficial for the uptake and funding of new and innovative products and thereby providing required care to patients in need. The particular French situation is likely due to the distribution of duties and power. Aiming for the best possible care the French legislator placed virtually all decision-making power in the hands of the AFSSAPS, an institution which does not have to consider the price and accruing costs of a product or treatment but which merely focuses on the efficacy and effectiveness of a treatment method in a very transparent way based on publicly accessible data and in interexchange with all other involved stakeholders. The formal liability of the AFSSAPS to report final decisions to an expert committee within the MoH and the opportunity to appeal decisions made by the AFSSAPS assure accountability to a great extent.

3.3.2 “Regular Supplementary Reimbursement” – Vanquishing Technical weaknesses of Patient-Classification Systems

Similar to the additional funding provided for innovative high cost drugs which have been newly launched but which cannot be funded by existing case groups, there are regular supplementary funding measures for those drugs which are difficult to map in patient-classification systems in the short to medium term for technical reasons. The difficulty to map high-cost drugs is due to the fact that the need to administer them just occurs rather irregular but their prices are so high that the integration of their prices into the cost-prices of case groups would cause either an over- or underfunding of the particular case-group. Besides, these kinds of drugs are not easily assignable to only one case-group but their administration may be possible for treatments mapped in several case-groups.

Differently, from the decision-criteria applied to decide about the granting of innovation-remuneration the criteria applied to decide about supplementary reimbursement go further and priorities differ significantly. Thereby each of the examined countries is following, in fact, comparable strategies, which however differ in their outcomes, as will be shown, among other things, below.

3.3.2.1 Germany: “Zusatzentgelte”

The “hospital financing act”¹³ provides in §17 (1) the possibility to stipulate in limited exceptional cases supplementary reimbursement for activities, aggregated activities or drugs where that appears to be necessary for the supplementation of the DRG-budget. Originally “they were devised in 2003/2004 for university hospitals, highly specialized hospitals and maximum providers which were facing too less base rates” (Respondent 1). In order to adjust these base rates, high-cost products were excluded from activity-based reimbursement. The reasoning was rather simple and refers to one of the weaknesses immanent in all patient-classification systems: “if a provision displays

¹³ Krankenhausfinanzierungsgesetz

merely 5% along several DRGs then there will be a tilt, i.e. in university hospitals 20% and in regular hospital 0%, thus some equalization measures were needed – the supplementary reimbursement” (Respondent 2). The interviewed experts emphasized that the establishment of supplementary funding was highly reasonable in terms of removing the political pressure from the G-DRG-system even though they do not fit the system’s actual construction and underlying idea, as will be discussed later.

All activities and products which satisfy certain conditions are reviewed by the Institute for Hospital Reimbursement (InEK) for eligibility of supplementary reimbursement. These conditions are: 1) Spreading over several DRGs 2) Sporadic appearance without a defined assignment to a DRG 3) Definable activity with explicit identification and accounting characteristics 4) Relevantly high costs 5) Structural tilt at providing the activity. The very most innovative and new products that are not able to be integrated into DRGs are converted from NUBs to supplementary reimbursement. The figure below exemplarily points out the path a new product will have to go until it is established in either a DRG or as supplementary reimbursement:

The cumbersome Path from alternative to regular Reimbursement

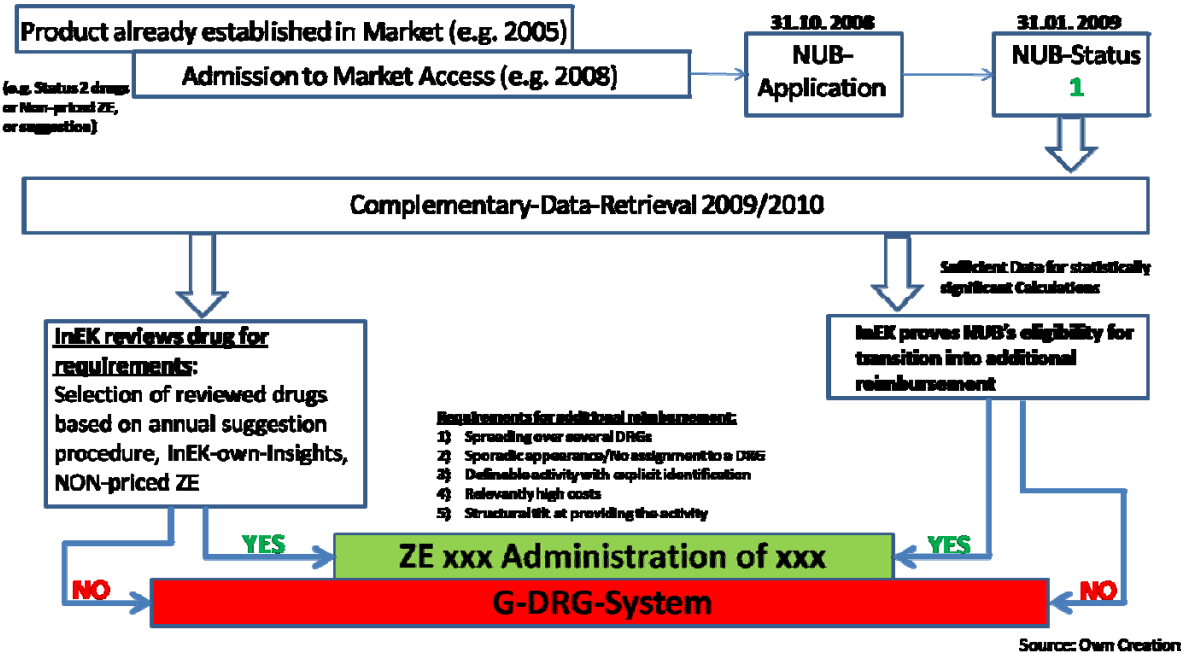


Figure 3.3-3: The Long-term Financial Establishment of Drugs in Germany

From a practical point of view, both the hospital pharmacist and the representative of the pharmaceutical industry were confirming that there were hardly any products needing more than 3 years to be integrated into the regular system. “Until now it was always possible to create a supplementary funding via NUBs within 3 years – at least for the important drugs which are really needed. Drugs which aren’t urgently needed won’t be used and eventually disappear – what’s

reasonable” (Respondent 2). That mechanism is well communicated and understood by most of the stakeholders and provides certain predictability to hospitals and pharmaceutical manufacturers.

By publishing an annual final report that includes a rather detailed and exemplary description of changes and processes clarifying the conversion of products initially remunerated for by means of NUBs towards supplementary reimbursement, the InEK attempts to satisfy accountability concerns. However, there is no reasoning explaining why some products are granted supplementary reimbursement and others not. The granting of supplementary reimbursement is mostly considered as arbitrary and very much depended upon single decision makers which base their decisions on rational as well as political reasons. In fact, “the system is so complicated that merely 10 people understand the decision-making. If those 10 people are smart they will say: ‘well, the decision-making is not very fair, yet it is all about the higher good that the entire system is working’” (Respondent 1). Thus, for instance the creation of supplementary reimbursement for breast cancer diagnosis which is worth 2000Euro was refused. “There was a political consensus that one was not willing to open door and gates for additional reimbursement in that amount of diagnostic activities. Besides one could always argue that merely one or two DRGs are concerned and thereby the required criterion of supplementary reimbursement applying to several DRGs is not fulfilled” (Respondent 1). In contrast there are products granted supplementary reimbursement for the reason of competition, as already outlined above, even though these products did not comply with all of the defined criteria either. As there are no explicit and specified guidelines or a defined threshold in order to decide about the establishment of supplementary reimbursements the “rules of the game” are not always applied consistently but decisions are motivated by the political setting of priorities. Yet, priorities may change depended on single decision-makers and the environment they are made in, what causes intransparency. The only stakeholders other than the InEK and official appointees, who may have a chance to influence priorities and the decision-making, are medical specialized organizations. In fact, these do not directly participate in a decision-making process, however they can affect decision outcomes indirectly by e.g. changing their guidelines in favor of the drug considered or rather substantiate the necessity of a product publicly. It turned out that hospitals and manufacturers generally do not have these opportunities as they are not asked to participate nor do they have any opportunity to approach the InEK during that state of decision-making (Respondent 1 + 2). Nevertheless, there are hints advert to an implicit approximate threshold, even though as shown above there are more considerations taken into account when making decisions. The threshold can be concluded considering the NUB procedure and by taking a look into the annexes of the case fee catalog which comprises of several lists for supplementary reimbursements.

As it can be concluded, there is an opportunity to predict the time until a drug will be finally established within the G-DRG-system. Based on the criteria and drug’s costs there is even a potential to forecast whether the drug will be mapped in one or more DRGs or whether it will be eligible for

supplementary reimbursement. However, all possible forecasts will lack certainty due to a lack of transparency caused by the influence of priorities and a lack of information.

3.3.2.2 *England: “Payment-by-Results-Exclusions” (PbR-Exclusions)*

In general “any drug that isn’t explicitly excluded from the scope of PbR will be somewhere included [in the national tariff]” (Respondent 13). This very often quoted statement applies to a number of high-cost drugs that are typically very specialist. The drugs are excluded from the scope of PbR as the existing HRG classifications would not necessarily allow for a fair reimbursement (PBR guidance 2009/2010) due to different severities of patients’ conditions. Thus, e.g. “for people who have difficulties controlling diabetes treatment: there is a very expensive pump which is delivering a constant amount of insulin – it’s an extremely good treatment, but excluded from HRGs; even though the insulin is included; you have to apply separately for the device” (Respondent 14). In general, there are two explicit criteria applied to separate high cost drugs from drugs, devices and services which are covered by HRGs:

- 1) the drug has a disproportionately high-cost share relative to the costs of other expected activities within the relevant HRG and
- 2) there is, or is expected to be spend more than £ 1.5 million in England or 600 cases in England per year on the drug (PbR guidance 2009/2010; Pate 2009; Respondent 13; DH Managing your organization 2009/10).
- 3) A further, often stated, criterion is the sometimes “extreme variability of HCDs” which would make it difficult to convert the costs of an HCD in an average HRG price (Respondent 11+13). In other words the unpredictability of costs accruing by the administration of an HCD depends on the individual treatment dosage and the length of the drug-related treatment.

The stated criteria provide all involved stakeholders with a rather transparent and clear image of drugs that do qualify for a PbR-exclusion. Generally, there were no concerns regarding the exclusion of a drug mentioned by the interviewed experts, i.e. if a drug complies with all the criteria the DH will exclude the product from PbR without attempting to avoid exclusion. In fact manufacturers and hospitals are well informed and may predict rather detailed how a product will be established regarding the way of reimbursement in the clinical practice. Whether the material details, (i.e. there is, or is expected to be spend more than £ 1.5 million in England or 600 cases in England per year on the drug) are reasonable values is difficult to assess. There is no publicly available data that would allow for retracing the thinking and considerations which were taken into account making that decision. Nor is there any reasoning explaining the selected values. Besides, none of the interviewed experts was aware of a participation of stakeholders others than the DH in determining the number. Yet, having a defined value provides manufacturers with a favorable initial position in price considerations.

Most PbR-excluded drugs may be found on the DH's annually revised and published high-cost drug exclusion list¹⁴. However, due to the background that the HCD exclusion list is not updated during a financial year in particular new in-year drugs will not be considered within the list for at least some time. The DH even states explicitly: "any new drug that is added to an excluded category in the BNF will still be excluded, but may not be included on the list" (PbR guidance 2009/2010). This situation may cause uncertainty and practical intransparency in the clinical prescribing practice and might hinder the administration of a drug not mentioned on the list as physicians would naturally look out for cheaper alternatives as they emanate from the assumption the drug would have to be financed from the hospital's HRG-budget.

That list, however, would have to be appreciated more like a recommendation to PCTs. That is the listing of a drug as a PbR-exclusion does not necessarily mean that the drug is not automatically eligible for reimbursement or will be funded by commissioners, as for instance happened very often with the TNF alpha drug Infliximab before it was appraised positively by NICE. Applying such kind of approach all responsibility and accountability is shifted to PCTs away from the central level. As all prices for excluded drugs as well as their eligibility to be reimbursed are negotiated between providers and commissioners locally, hospitals face the problem not to have the certainty of predicting the eligibility to administer the drug and receive funding while manufacturers cannot count on secure revenues. Manufacturers do not even have the chance to influence the negotiations as they are not asked to participate in the decision-making process. Besides, variable decision outcomes differing from PCT to PCT put patients in a situation of post-code-lottery. Patients are usually tied to a particular PCT and likely there is a lack of transparency concerning the differences and conditions of available treatments within a PCT so that patients do not even have the chance to make informed decisions but are extradited to arbitrariness. An interesting case study conducted by Mehta and Low in 2007 researching the administration of Bortezomib – a chemotherapy drug for the treatment of myeloma - in private and NHS patients confirms the findings of this research. Mehta and Low reported that the current funding decisions on the local level may be considered as strongly arbitrary. Among PCTs there are wide disparities in access and availability of chemotherapy caused by different priorities and budget considerations. According to Mehta and Low funding decisions of PCTs turned out to be quite inconsistent as they state: "patients with identical needs, attending the same clinic, will receive different responses to applications for new drugs depending on which PCT is responsible" (1997). Interestingly all refusals to fund the treatment with Bortezomib were taking place in England while PCTs in Scotland and Wales were more willing to consider the reimbursement of chemotherapy treatments.

In most of the cases additional payments will only cover the hospital's acquisition costs of the excluded drug including assumed local discounts. Similar to PTPs it remains intransparent based on which data the PCT develops its assumptions. While hospitals have to provide all possible information

¹⁴ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_094091

in order to receive funding PCTs are virtually accountable against no one and may decide what information they are willing to enable to hospitals and to the public.

As it can be concluded, at the first glance regulations concerning the eligibility for supplementary reimbursement appear to be considerably transparent, although, the substantiation cannot be retraced. However, again, due to the fact that all responsibilities and accountability are shifted to the PCT, there are planning insecurity for hospitals and manufacturers and a post-code-lottery situation for patients in need. PCTs cannot be hold accountable for their decision-making regarding the funding and reimbursement of high-cost drugs.

3.3.2.3 France: “Tarification à l'Activité” – Excluded drugs (T2A-exclusions)

In France most drugs and activities related to drugs are currently financed by funds based on GHSs. In particular the use of cancer drugs such as Trastuzumab, Rituximab, Gemcitabine and its generic versions but also drugs derived from blood, expensive antifongics, anti TNF alpha drugs and others are hardly affordable in hospitals just from the payment per case rates. Thus, a limited number of about 125 expensive drugs are excluded from the GHS payment system. All excluded drugs may be found on the so called T2A-list. In order to ensure that hospitals have access to those new and innovative treatments the Social Security Funding Act from 2004 established the possibility to finance costly innovative drugs delivered in inpatient care on top of the GHS tariff. Thereby the principle applies that drugs which are funded additionally are reimbursed to hospitals up to 100% of their purchasing price but within the limit of a ceiling price defined nationally (Respondent 8). The additional reimbursement or rather the consideration of including a drug on the T2A-list will just take place if three major conditions are fulfilled:

- The drug's costs have to be particularly high (Michelot 2005)
- The product in question would introduce heterogeneity within the GHM-costs of GHS-tariffs (Or et al. 2006)
- “The drug is not indicated to all patients included in the DRG” (Respondent 9)

The inscription of a new high-cost drug on the T2A-list, however, does not happen automatically. In fact there is no formal application procedure but all drugs that are admitted to reimbursement are examined by expert groups at the Ministry of Health or like one of the leading German DRG-experts stated: “Ladies and Gentlemen, do you actually know how in France reimbursement decisions with regard to new and costly innovative drugs are made? There are a couple of older gentlemen catching up in the 6th arrondissement. When leaving the room - after a couple of days - all of the sudden they have got a list [of excluded drugs]. No methodology at all”. In fact every one of the interviewed experts was providing similar statements. There are semi-public criteria the Ministry will base its decisions on, these criteria or even explicit thresholds will not be disclosed as there is “the fear that the industry would start playing games with them [Respondent 8] or would manage to have a price above the defined threshold” (Respondent 9). Yet, the fear that an important

drug could not find its way on the excluded drugs list is of minor concern compared to involuntary reductions in the drug's price, as the interviewed expert from the pharmaceutical industry stated. From time to time transparency and accountability issues are to deplore, however they do not have a strong impact on the uptake or the eligibility of the funding of a drug. According to the interviewed representative from the Ministry of health the inscription as well as the radiation from the T2A list is even following rather transparent criteria. Thus the main criteria which are taken into account in order to decide about the eligibility of additional reimbursement are the earlier mentioned statistical criteria but also medical criteria, (i.e. the predictable impact on medical practices of the integration into the GHS tariffs or additional payment) and of course economic criteria such as the budget impact and the cost of treatment. All of those criteria might have been assumed, however, the reasoning or rather the actual and explicit definition of at least the medical and the budget impact criterion is lacking. Thus, it is difficult to predict what amount of costs accruing with the administration of a drug and what degree of change within the medical practice are considered as acceptable or rather unacceptable by the Ministry of health. The Ministry was rather clear about the goal to have as few drugs as possible on the additional reimbursement list, since every new drug is an additional expense to them. The actual objective is even to have no drug at all on that list and to integrate them into GHS tariffs in the long run. However, the patients' access to new and innovative treatments has to be assured (Respondent 7+8).

Once the Ministry of Health has decided on the drugs inclusion on the T2A-list the drug's funding is virtually secured and the drug's uptake can happen immediately. In general the Ministry of Health makes its decisions rather quick within six months. Different from the tariff update the T2A-list is being reviewed constantly also during the year to take into account the drug's life-cycle and the development of the tariff system. Consequently, that may result not just in the inclusion of a new and innovative product when it is launched on the market but also in the opposite, i.e. in the removal of the product from the list when its use generalizes and when the GHM classification evolves (Respondent 8). By law all decisions made by the Ministry will have to be published and are accessible on the Ministry's website. The underlying reasoning however is not required and will not be accomplished as mentioned already above. That, again, causes a lack of transparency as decisions cannot be retraced back, nor is there any base of argumentation in case manufacturers and hospitals do not comply with the ministries decision-making. Thus, the Ministry avoids being hold accountable to some extent.

Economic regulatory measures are stipulated in a framework agreement between the pharmaceutical manufactures' union (LEEM) and the Economic Drug Committee (CEPS). This framework agreement regulates among other things price-setting procedures. While most pharmaceutical products for inpatient care are freely priced the prices of all drugs which are included on the T2A-list are regulated. Thereby, France is following an approach called "price registration procedure". The price-setting procedure does not impact the actual availability of the drug to patients in need, however, may have an impact on the manufacturers estimated revenues. By means of a price

registration procedure a pharmaceutical manufacturer proposes a price to CEPS. The proposed price supposes to be in line with the product prices asked in Germany, the UK, Italy and Spain. CEPS does have the opportunity to refuse the registered price within the next 15 days on ground of a price too high compared vis-à-vis the comparator drugs or prices elsewhere in Europe. In that case the price will be fixed by Ministerial decree. The resulting so called nationally agreed 'ceiling price' will finally serve as the margin for reimbursement by hospitals. Accordingly, if a hospital purchases a drug to a price higher than the ceiling price the difference cannot be billed to health care insurance funds. In contrast, if a hospital purchases a drug to a price lower than the ceiling price the bonus will be shared equally between hospital and health insurance fund. In order to allow for that practice, even though prices are regulated on the national level, hospitals are hold responsible to carry out their own procurement by either negotiating with pharmaceutical manufacturers or through tendering (PPRI 2008). Even though the industry is not very warm to that mechanism of price-setting (Respondent 7) all regularities are rather transparent as a rather clear methodology is followed by the CEPS.

As it can be concluded, in France the granting of supplementary reimbursement shows transparency and accountability issues with regard to the exclusion of a drug from the GHS-system. However, even though these issues are not favorable they do not impact the time-to-patient-access or the certainty of assured funding negatively.

Information provided in this chapter will be essential in order to comprehend the subsequent analysis of governance elements for the purpose of determining the acceptability of regulations and decision-making processes embedded in the regulatory frameworks of each country respectively. Thus, the provided insights regarding funding and reimbursement measures as well as the decision-making processes which are taking place are indispensable to accomplish an analysis with explanatory power.

4. ANALYSIS

The scope of decision outcomes in healthcare is very often constraint through the involvement of several stakeholders following diverse interests in decision-making processes. Yet, often there is no equilibrium in power and competencies so that some stakeholders are able to assert their interests better than others. In order to provide lesser influential stakeholders with some certitude too, most often fine-meshed regulatory systems are in place which define more or less concrete the role, competences, rights, responsibilities and power of each involved stakeholder. These fine-meshed regulatory systems further do not only determine the setting but also processes and interactions which occur within those settings. Hence, regulatory measures taken by particular stakeholders or decision outcomes are limited in their scope depending on how a regulatory framework is defined.

In general regulatory frameworks attempt to equip all stakeholders with the same share of power. In fact, the idea of regulatory frameworks is to constrain regulatory arbitrariness and to resolve conflicts that arise in relation to these constraints and thereby rather the set of standard requirements such as “[...] the efficient provision of services to consumers at the minimum necessary price; and [to] support private investment by continuing to allow companies the reasonable expectation of a normal real rate of return” (Stern&Holder 1999; p.38).

How good or bad regulatory arbitrariness is constraint and thus how favorable or rather counterproductive regulatory measures and decision outcomes turn out, can be analyzed on five essential criteria which cover a broad range of issues perceived as being necessary for good quality regulation. These criteria - “clarity of roles and objective”, “accountability”, “transparency”, “participation” and “predictability” - are strongly interrelated with each other but are assignable to subordinated notions of formal and informal accountability. “One way of distinguishing issues of formal accountability from those of informal accountability is to make the distinction between matters of institutional design and of regulatory processes. Another, and perhaps more helpful, is to distinguish between the formal attributes of the framework—as written in the letter of the law—and the practical application of the framework and how it is interpreted—the spirit of the law and how well it is kept” (Stern&Holder 1999; p. 41). Regulations and decisions concerning the funding and reimbursement of expensive inpatient drugs will be analyzed with regard to both notions of accountability: formal accountability regarding issues concerning the institutional design and informal accountability dealing with the quality of processes.

4.1 Formal accountability

The “focus on institutional design, emphasize[s] issues of formal accountability, e.g. in the design of legal frameworks and the formal structures of legal systems” (Stern&Holder 1999; p.41). Considering the three examined countries major differences occur in the level of institutional organization, i.e. with regard to responsibilities, roles and duties within the hospital financing systems.

In all three countries different regulatory models may be discovered and classified according to Byeme (1998) as: a) a highly centralized model directed by the Ministry of health with several arm-length bodies working on behalf of it in France; b) a more decentralized one in Germany with functional actors such as sickness funds, hospital associations and the InEK; c) a para-governmental model of regulation in England with highly autonomous actors. Whether and in how far the different regulatory models impact the quality of hospital financing regulations with regard to the institutional design will be analyzed below.

4.1.1 Clarity of roles and objectives

Stern and Holder pointed out, that all models of regulation may be legitimate and good forms of regulation, i.e. neither the model of economic regulation nor the degree of governmental interventions do necessarily impact the quality of regulation, however the regulator should grant “regulatory principles (e.g. on tariff revision) this can provide some protection against regulatory opportunism” (Stern&Holder 1999; p.39) as well as clearly state the objectives and provide a specific institutional framework that encompasses a clear definition of functions and duties of all involved stakeholders comprising of decision-making power.

When applying these insights to the practice exercised in the examined countries the satisfaction of requirements for good-quality regulation appears more difficult to accomplish if decision-making power is delegated away from the central level towards a regional one without realising a clear division of duties and power as has been observed in England. Thus e.g., “[...] the establishment of a credible independent regulatory agency has become a standard feature [...] in Europe” (Stern&Holder 1999; p.37) which is accomplished in France and Germany by concentrating all general regulatory tasks concerning hospital financing at ATIH (Technical Hospitalisation information agency) and InEK (Institute for Hospital Reimbursement). “This provides the signal by which private investors, [...] are reassured that they can expect to earn a reasonable real rate of return” (Stern&Holder 1999; p.37). In point of fact ATIH and InEK are rather independent in exercising their duties from governments and ministries whereas the intensity of the connection to the government differs nevertheless significantly. According to that, the German regulative authority InEK in contrast to the ATIH does not work on behalf of the government but on behalf of hospitals and sickness funds. In fact the ATIH was established as an arm-length body what is allowing for “a considerable degree of independence from ministries” in order to provide “some guarantee against arbitrary political interference by governments” (Stern&Holder 1999; p.39). Nevertheless, the influence of the Ministry of health remains strong, considering e.g. the way of how excluded drug lists are derived and prices of excluded drugs are negotiated. The tied connection of ATIH and MoH enables the Ministry to reserve the right to directly interfere with methodology-based considerations of the ATIH and eventually to make possible contradictory decisions influenced by cost-containment priorities such as the goal to have as less drugs as possible excluded from activity based reimbursement.

Despite similar duties and responsibilities of ATIH and InEK, the situation turned out to be quite different in Germany. The InEK cannot work on behalf of one stakeholder or try to implement decisions related to certain priorities which have not arrived at a consensus along all stakeholders involved in the financing of hospitals. As a matter of fact the InEK has to fulfill an obligation against all stakeholders and has to work on behalf of both sites providers and sponsors of healthcare. The InEK thus has to provide regulatory measures that allow hospitals to administer high-cost drugs without disregarding sickness funds' demand for cost-control. Moreover it is perfectly independent from political and governmental interference as the principle of self-administration is applying and decisions involving the government are made on a higher level. This situation sets a rather defined frame for the work done by the InEK without leaving much space for arbitrariness. The regulative situation accomplished in Germany is a favorable one as there will not be any extreme decisions but the balance will be retained by the InEK and due to the constellation of diverse interests most of the regulatory responsibilities are delegated to the InEK causing a holistic regulatory setting where most of the time stakeholders are in concert with each other. In terms of categorizing or ranking the German DRG-system as well as the French T2A-system (Pricing per Activity) with respect to the criterion "clarity of roles and objectives", it can be concluded that roles, responsibilities and decision-making capabilities are well-articulated and clearly separated from each other. Objectives, goals and priorities are clearly stated and publicly accessible as well as assignable to a particular stakeholder (A), although in France there are doubt left to the effectiveness in practice (B).

In England, on the contrary, the ability to make decisions is widespread. In fact, decision-making power is primarily left to diverse regional working groups within PCTs. Yet, it remains difficult to identify participants of these working groups and to determine the scope of independence with regard to their decisions and how these relate to objectives defined and orders given by the DH. Even though objectives and goals are comparable well defined in all countries, in England the accomplishment of these objectives has a diverging character as regional decisions are influenced by local priorities and the centralized framework does not determine decision outcomes sufficiently. That regulatory arbitrariness or opportunism becomes apparent in for example the way reimbursement tariffs and hospital budgets are derived at or in the way innovation remuneration for innovative drugs is granted. The "process of regulation tends to become a shifting set of negotiations between the players. "Regulation and end-user pricing in particular, tend to become highly politicized" (Stern&Holder 1999; p.36). The consequence is that prices of drugs are not determined in a commercial way "but that any financial targets are set in terms of financing current expenditures" (Stern&Holder 1999; p.36). Indeed, in France and Germany, drug prices are not determined in a commercial way either just because of the general way health care is financed, i.e. the involvement of a third party payer in both of the countries, however, in contrast to France and Germany, decision outcomes in England are more arbitrary as these rely on several single decision-makers that ambiguously follow other than merely a regulative task or rather the financing of care. That situation

is primarily due to the concentration of goals in one and the same hand. The same challenge may be observed in Germany with respect to innovation remuneration as well, but also the flipside which accounts for at least 96% of all hospital revenues. Thus, DRGs and the prices of supplementary remuneration are determined by the InEK which is only focused on methodological parameters and the capability of the overall system to work without paying respect to any kind of effectiveness, efficacy or efficiency matters of a treatment. While that favorable principle applies overall to both of these funding measures the separation of methodological regulation and the financing of innovation is enfeebled. Indeed, the InEK is assessing new drugs according its methodology, however, even if a drug is found to be new and not sufficiently funded through the existing measures, no obligation to fund the new drug is derived from the assessment as it is the case for both of the other funding measures. Instead, sickness funds are eligible to reject the funding of new drugs or rather negotiate the terms of funding individually with each hospital and in their own favor. By dissociating the obligation to finance health care from the regulatory measures taken by another stakeholder, that is actually thought as a “corrective” to the budget-driven priorities of sickness funds, sickness funds of course tend to follow their priorities and find themselves in the same situation as English PCTs in general. Thus, legal provisions exist on regulation, but neither these nor established practice introduce a real division between regulation and government/sponsor or eliminate significant ambiguities (C).

The importance of the criterion “clarity of roles and objectives” is not just to underestimate from the above discussed point of view, but there are further important interrelations to all the other criteria as well, thus e.g. “both accountability and predictability will be significantly enhanced if regulators’ objectives are clearly stated, enabling them to be challenged if they depart from these objectives” (Stern&Holder 1999; p.43) as will be analyzed next.

4.1.2 Accountability

Accountability “requires that regulators’ decisions can be challenged in an effective way, if, for example, certain decisions are thought to be unfair or incompetent. “If such appeals mechanisms exist, this will reduce the risk of firms being treated unfairly (or randomly, as a result of incompetence)” (Stern&Holder 1999; p.43). That axiom does not require necessarily the existence of a particular instance nor a specific legal setting in order to ensure a minimum of accountability as the ideas and practices of accountability and on a higher level of law and justice evolved historically and may differ significantly. According to that, traditionally, in England there is no emphasis on a “formal constitution, no formal code of administrative law and a tradition of aiming at compromise between parties rather than reaching for the law-courts” while the German and French regulatory systems “operate within Napoleonic law codes and within traditions of activist states and strong public service obligations (Stern&Holder 1999; p.34). Because of these obvious divergences Stern and Holder defined several general criteria to be accomplished in order to satisfy accountability requirements.

When dealing with accountability in health care or more specifically hospital financing, two dimensions have to be distinguished. The first is the regulatory dimension concerning primarily the relationship between the regulatory agency and the health care provider or rather sponsor and a second subordinated one, in which interactions between health care sponsor/provider and patients/pharmaceutical manufacturers are taking place. That distinction is important as patients and pharmaceutical manufactures do not have a possibility to challenge decisions made by a regulatory agency legally but merely (at least in the best case) a shortage of health care or quality. In fact InEK and ATIH can only be approached officially by the MoH, hospitals and sickness funds and not by any other stakeholders. Indeed, ATIH and InEK have to comply with a certain accountability standard and are “accountable, for example through the legal system, for any failure on [their parts to fulfill their] statutory obligations” (Stern&Holder 1999; p.43). That happens primarily “via the submission and discussion of an annual report” (Stern&Holder 1999; p.43) migration tables and the delineation of implemented regulations directly linked to statutory decrees. Thus, in France all tariffs estimated by the ATIH are a matter of indirect revision by the parliament when health expenditure budgets are annually determined. In fact, in both countries there is something like an inner liability check of tariffs and cost-weights estimated by InEK and ATIH. While in France the liability check is accomplished by the parliament where heterogeneous interests are represented, in Germany the InEK fulfills a moderate task by its nature aware of the challenge to meet the demands of two stakeholders following divers interests – sickness funds and hospitals. Consequently, with respect to patient-classification and prospective hospital budgets, accountability is accomplished in terms of reasoning the decision-making but the arrangements fall short of a fully effective degree of accountability considering the scope of manufacturers and patients’ to appeal and to readdress disagreement (B).

This situation becomes problematic considering e.g. the granting of supplementary reimbursement for innovative high-cost drugs or assuming a DRG or rather GHS to be priced too low to provide the best possible care or at least a necessary standard of care. At least pharmaceutical manufacturers can estimate whether a hospital is able to administer a high cost drug given its DRG-budget or whether it is not since the DRG was calculated too low, no supplementary reimbursement was granted and sickness funds reject to finance the treatment on an individual basis. Even though, there is suppose to be a legal institution to challenge the decision made by the regulatory authority directly, in practice a manufacturer merely has the chance (through patients) to legally claim a review of sickness funds’ funding decisions and quality of care provided through hospitals. Thus, any failure in regulation would have to be addressed via MoH, sickness funds or hospital associations which of course try to cover the authorities working on behalf of them. Amongst other things this is simply due to the fact that none of these institutions could be hold accountable for the decisions made by InEK and ATIH, i.e. there is no level of jurisdiction.

Drawing back on the “clarity of roles and objectives” discussion, from a patient’s or firms point of view, a similar accountability frame applied in England, exists in France and Germany - the

relevant law provides for specific means of redress for aggrieved parties, but the degree of accountability to other bodies is inadequate (C). Although, in France and Germany a separation of regulatory and executive tasks and duties is practiced, the default of providing a formal mechanism of accountability on all and over all levels of regulation, finance and provision causes the same accountability frame as in England. In England all responsibilities and accountability are virtually shifted to the PCT which is in charge of both providing and financing health care. The PCT is in charge of deciding about the costs and volumes a hospital is allowed to produce, which drugs are to be administered preferably and which ones are not. All interviewed experts perceived decisions made by PCTs and German and French sickness funds as highly arbitrary and priority-driven. In all three of the countries there are jurisdictional levels where failures can be brought to review. However, sickness funds and PCTs comprise of an immense power and influence and just in very less cases they are not able to substantiate their decisions in at least some way – which often applies if they want to preserve a process of decision-making that would be endangered if they would try to justify their decisions legally (will be later discussed). In fact, only recently there is a tendency to publish full statements of accounts in the first instance and thereby prevent any legal claims. This tendency, however, seems to be more advanced in England than in Germany and France and is also comprehensible considering the way the health care systems in general and health care financing in particular are organized. According to Stern and Holder, accountability also exists to some degree if firms and patients are able to comment and exert influence on informal ways. Patients in England have another appreciation and understanding of their rights and the duties which have to be accomplished by the NHS. Thus, they tend to exert more influence via audit commissions, patient associations and the media if there are any general problems concerning the quality and finance of health care and are often successful with their claims as it was in the case with the funding of the cancer drug Herceptin®. This kind of self-conception is not so pronounced in contribution-based health care financing systems with several sponsors and the possibility to change the sickness fund in case of dissatisfaction.

4.2 Informal Accountability

“The key attributes of informal accountability are specified as the degree to which the regulatory process: encourages debate and open discussion; involves all relevant parties; leads to justification by the regulator of decisions and methodologies; and generally leads to a clear understanding by all participants of the “rules of the game” (Stern&Holder, 1999; p.42). The accomplishment of these key attributes has to be seen in the context of the above discussed criteria of formal accountability. Yet, the quality of regulation and decision outcomes can also be assessed by taking into account the informal accountability criteria transparency, predictability and participations. These will be discussed in the next section.

4.2.1 Transparency

Based on the discussion dealing with creation of formal accountability, Stern and Holder clearly pointed out the significance of informal accountability factors such as transparency. Transparency is decisive for a successful accomplishment of satisfying formal accountability standards as “a requirement on regulators to explain their decisions and processes should reduce the likelihood of unfairness or incompetence. [...] transparency is crucial for ensuring effective accountability, since regulated firms and others will have a better understanding of regulators’ reasons for making certain decisions, and will therefore be more confident in their ability to challenge some or all of those reasons” (Stern&Holder 1999; p.43).

Following up on that conclusion and applying it to the situation already discussed regarding accountability, again, in France and Germany two different qualities of transparency can be observed, primarily due to the shift of influence and competence within the system. Thus, depending on the level of regulation or rather decision-making major regulatory documents and the reasoning behind major decisions are more or less published and accessible to the public discussion. On the regulatory level, both regulatory authorities, InEK and ATIH need to publish their decisions and stipulate regulatory standards, already because of formal accountability requirements (B). Also the English DH is providing an insight to all regulatory documents concerning the methodology of estimating HRGs for reasons of accountability obligations to all members of the NHS. As those are matters of discussion, also reasoning is given at least up to a certain degree. Yet, re-traceability and transparency issues seem to be apparent nevertheless concerning the applied methodology (C). As a matter of fact patient classification systems are constructed quite complicated and just rather few people have a more comprehensive understanding of how these systems work, what provides regulatory authorities with the opportunity to accomplish regulations or decisions which are not always in line with the publically accessible methodology. In England, due to the maintenance of patient classification systems through varying expert working groups from the entire NHS, regulatory decisions concerning the system’s design and attributes may be even more divergent and intransparent as involved experts approach primarily problems which evolve in their own practice. Yet, since all parties, which are concerned by those decisions, are aware of the fact that all working group members belong to their own community the degree of accepting intransparency is more pronounced. Besides, the degree of informal transparency can be assumed to be higher as it is the case in France and Germany where regulatory authorities are more difficult to approach. And also Stern and Holder asking “if decisions/reasons are not published, are any participants (such as the firms themselves) told of the reasons for major decisions?” (Stern&Holder 1999; p.50).

However, the research showed an increasing lack of formal transparency in more decentralized systems, which is, not due to a “bad will” but due to the formal regulatory setting. Yet, in all countries decisions are published. Nevertheless, the majority of stakeholders are lacking the insight and knowledge to challenge such decisions. Thus, in other words there are several DRGs which have an

extremely lower price than the actual costs, collected in the clinical practice, are. Most of the time regulatory authorities justify that situation by referring to the systematic of the overall system without being more concrete and their reasoning is generally accepted. However, this does not necessarily have to be a disadvantage regarding the ability to administer drugs in the clinical practice. In fact, drawing back on Stern and Holder the consideration of a holistic context is decisive. Also Stern and Holder emphasize “a fair but incompetent regulator is not necessarily better (and may be a lot worse) than a biased but competent one” (1999; p.44). Usually, in all three of the countries no new drugs are excluded from the system a priori but mapped at least to some part somewhere in one or more DRGs, even though it is not always transparent where exactly. This situation reflects a particular priority setting, which is considerably comfortable for a pharmaceutical manufacturer. Of course there are other matters constraining the uptake and use of innovative drugs, however there is no such thing as a general constraint with regard to the methodology of calculating DRGs.

More transparency, however, is a requirement all three countries should consider with regard to the way decisions on excluded high-cost drugs are made. The factual information in chapter 3 has shown that those decisions are often influenced by budget concerns and often a matter of regulation which is blended with financial considerations. The greatest lack of transparency thereby occurred where responsibilities are shifted fully away from the regulatory towards the finance level as it is the case in Germany regarding innovation remuneration and in England in general (C). As already delineated above, in both of the countries the granting of supplementary remuneration is matter of individual negotiations between sickness funds or rather PCTs and hospitals.

Although hospitals are an institution of formal accountability in the process of formal regulation with the right to screen all relevant documents, in the negotiations for prices and volumes of high-cost drugs hospitals’ power is diminishing compared to the power of PCTs and sickness funds. In these kind of asymmetric relationships hospitals are subjected to the “good will” of PCTs and sickness funds to have the funding of a high-cost drug granted. In fact there are no obligations and plenty of opportunities to reject funding. Yet there is no necessity to disclose reasons or decision-criteria why funding was rejected. The lack of transparency is an often and long stated criticism by hospitals. Surprisingly, there were no improvements regarding the transparency. Regional HTA groups within PCTs and sickness funds may even keep their reports and recommendations disclosed. Likely because of, PCTs and sickness funds enjoy a political rear cover which allows for the lack of transparency.

As has been already concluded above with regard to the clarity of roles and accountability discussion, the omission of regulatory levels or rather the shift of decision-making power towards sickness funds and PCTs without accomplishing a clear separation of priority-driven goals and therewith the ability to exert influence and make decisions takes transparency ad absurdum. Regulatory, political and economic goals get blended, yet often resulting in the domination to accomplish financial targets caused by daily and practical budget constraints.

From that point of view, the approaches found with regard to decisions made about the granting of regular supplementary remuneration in France and Germany appear to be essentially better and more beneficial for all involved stakeholders. Even though, transparency is lacking, supplementary reimbursement is determined centrally without blending political, economic and regulatory priorities for the most part. Thus, it is well re-traceable how prices of supplementary funding are calculated, by the German InEK and French CEPS, but the actual granting process and criteria are opaque (B). In fact there are similar criteria applied by the InEK and the French MoH in order to decide whether a high-cost drug is qualifying for supplementary remuneration, however those just allow for a general understanding while the actual decision-making is influenced by other factors such as cost-containment and volume consideration as well as the functioning of the overall system. That situation, however, differs from the situation in Germany with regard to innovation remuneration and England as virtually no financial concerns are precedent or at least not the driving factor, but the compatibility of granting supplementary remuneration with the overall system. Of course there is also in Germany and France the effort to have as many drugs as possible included in a DRG/GHS-budget, however, that is an a priori objective which every stakeholder is aware of. Thus the demand of hospitals and pharmaceutical manufacturers to define something like an explicit threshold is understandable. However, not having this threshold or clear and transparent criteria on which the InEK and MoH base their decisions can also be favorable in many cases. Thus, e.g. recently supplementary reimbursement was granted for several drugs which virtually had to be included in the DRG-budget based on their prices, but since there were tremendously higher priced competitors necessarily eligible for supplementary reimbursement, the InEK/MoH decided to go that way in order to not stimulate only the uptake and administration of the higher priced drugs. That decision and others are maybe arbitrary according the stipulated methodology and intransparent with regard to the applied criteria, however, not necessarily bad or disadvantageous for patients and pharmaceutical manufacturers. And besides, there is (informal) transparency to a certain degree which allows stakeholders an understanding why decisions have been made in a certain way. That degree on transparency, however, is differing between Germany and France, whereas the German InEK has to provide naturally, due to its formal positioning and dependence from hospitals and sickness funds, a more intense reasoning. Also Stern and Holder pointed out, that “it is certainly both possible and likely that an advisory and/or semi-independent regulator with obligations to publish and justify decisions may be more successful than a decision-making regulator in countries where the separation of powers is absent or limited” (1999).

4.2.2 Participation

The accomplishment of each single criteria discussed, i.e. “Clarity of roles and objectives”, “accountability” and “transparency” has a significant impact upon the quality of regulation in general. However, all discussed criteria, eventually have to be considered as a unit in order to be able to make a valid evaluation of how good or bad a system really is. Also with regard to participation this kind of

bilateral interdependence may be observed. While the successful accomplishment of participation is dependent from the embodiment of each stated criteria on the one hand, on the other hand the embodiment of these criteria can be of high quality just on the condition that several heterogeneous stakeholders effectively contribute to the improvement of the system. According to that conclusion, Stern and Holder (1999) understand by participation that all “relevant parties (including regulated firms, consumers and other industry participants) contribute effectively to the regulatory process, [what] should improve the quality of regulatory decisions and increase the likelihood of the regulator receiving both support and co-operation from firms, consumers and others. [Thereby,] Participation may take many forms, including formal consultation exercises, formal or informal hearings, and surveys of customer views and priorities.” (Stern&Holder 1999; p.43). Considering that definition, based on the analysis described by Stern and Holder, participation has to be summarized as poor in France and Germany. In fact, there is virtually no formal opportunity to participate for involved stakeholders in order to contribute to the work done by regulatory authorities, sickness funds and ministries and their decision-making with regard to high-cost drugs or drugs in general. This situation already results from the organization of roles, duties and the distribution of responsibilities and competencies in the inpatient financing system but also from the lack of transparency which disables most of the stakeholders to develop a thorough understanding of the system, system-relevant decision criteria and how the systems work in detail. The only exception is the maintenance of patient classification systems where hospitals are asked by InEK and ATIH during the annual collection of cost- and activity data to provide suggestions for improvement of the system, which are, however, often merely related to the medical aspects of patient classification but not to the economic ones. Thereby, however, hospitals’ “participation [is] meaningful, in the sense that participants [(hospitals)] [...] have a genuine chance of influencing decisions before they are made (rather than being invited to state their views on a decision which has already been made)” (Stern&Holder 1999; p.43). (D). A similar situation with regard to the development and maintenance of the patient classification system can be observed in England. Yet, the distinctively comprehensive structure and institutional organization of the English National Health Service entails the involvement and participation of peculiarly more stakeholders than in Germany and France where a higher degree of centralization limits the number of actors involved. But also in England, it is a rather closed and tied circle of particular stakeholders which are eligible to participate without providing a base of participation to patients and/or involved firms. Also in England no other stakeholder than a PCT alone has the chance to decide about the funding of drugs (C).

The failure to involve all concerned stakeholders sufficiently in the decision-making and provide the chance to effectively contribute to the system automatically causes a lack in the quality of providing predictable decision outcomes of both innovation remuneration and additional funding. Thus, according to the discussion above we will observe also in the discussion of the last criterion, i.e. predictability, two different qualities primarily depending on transparency and participation issues.

4.2.3 Predictability

The quality of regulation with regard to predictability is subjected to the scope of transparency provided and participation practiced in the different regulatory and decision-making settings discussed above. Consequently, and analog to the two discussed diametrically opposed regulatory and decision-making spheres, the extent of predictable regulatory outcomes and a conventional decision-making may differ significantly, i.e. on the one hand predictability is an imminent feature of activity-based reimbursement while some decision outcomes with regard to supplementary reimbursement are hardly to anticipate or predict.

Despite diverging levels of centralization in England, Germany and France in organizing activity-based reimbursement or rather maintaining and updating patient classification systems, regulatory principles which are formally set out, are comparable good. This is likely because of similar origins of activity-based reimbursement. Since the maintenance and update of patient classification systems requires a standardized and repetitive procedure of collecting cost- and activity data based on which DRG/GHS and HRG-prices are calculated, published timetables are most often met and outcomes can be anticipated. In all three of the countries the vast majority of decisions demonstrated a consistent approach. Even though there are sometimes smaller exceptions it is assumed that innovative or new inpatient services and drugs will be mapped in a case-group at least three years after they have been brought to market and that their mapping will be regularly updated. The same applies to the prices of case-groups which generally reflect the real cost of an inpatient service, product or drug rather detailed. In fact, there is an inherent need to set a sufficiently predictable regulatory frame with foreseeable decision outcomes. (A). As regulatory authorities in each of the countries need and want their decisions to be fully accomplished just because of financial reasons, they necessarily have to provide every other stakeholder to a sufficient extent with transparency and have to stick to the “rules of the game” in order to guarantee a smooth implementation of their decisions in the sub-systems of in particular hospitals. Just assuming hospitals would not be aware of when new DRG-prices are in place, but use the old ones or drugs are just arbitrarily mapped within the system the impact upon the regulator himself might be devastating and might cause immense financial consequences and public discussion broaching a critical shortage of care and the regulator’s inability.

The situation appears less favorable with regard to supplementary and innovation remuneration. Again there are extreme differences between both mechanisms of remuneration. While the French granting procedure of innovation remuneration is perfectly predictable – a paradigm of successfully accomplished predictability-regulation (A) – and also in Germany and France the granting of supplementary reimbursement is following a retraceable methodology with decision-outcomes that can be anticipated, the circumstances innovation remuneration in Germany and England as well as English supplementary reimbursement are granted in, do not allow in the vast majority of all cases for satisfying predictability. Again, depending on the degree of centralization, the concentration of competencies and the level of decision-making; predictability is more or less arbitrary. Where

diverging priorities and goals, i.e. the goal to accomplish good regulations, cost containment and quality of care, are blended and depend on daily practical budget constraints, decision-outcomes concerning the additional funding of high-cost drugs are simply arbitrary and difficult to predict also because of there are no transparent criteria which would make decisions foreseeable. Thus, as already delineated above, submitting a PTP-application for a new and expensive neurology drug to the PCT in East London where the prevalence of diabetes is eight times higher than the national average might turn out to be not very beneficial. The PCT would likely emphasize its local priority on diabetes and refer to the budgetary constraints which do not allow for the funding of a new non-prioritized drug. Subsequently, possible outcomes of the decision-making process may be either a “NO” , a “NO” for today but the grant of funding for a later date in time or the PCT will find a way to reduce expenditures elsewhere (Respondent 13). Because of the assumption that hospitals and manufacturers are not kept in the loop of detailed epidemiological and budgetary developments within a PCT, decision-outcomes may be unexpected and difficult to predict.

Besides there are 152 PCTs and about 190 German sickness funds, thus assuming a drug’s reimbursement is not regulated centrally an immense amount of specific and individual hospital applications and business cases for supplementary reimbursement would have to be administered, even though quite often just a rather few hospitals decide to apply. That situation very often results in a post-code lottery. That makes it hard for patients, physicians and manufacturers to predict which product they will be granted funding for eventually. Affordability considerations and distinct priorities of PCTs and sickness funds have an impact on the equal access to new drugs in the hospital practice. In fact, there is neither a consistent approach noticeable among the decision-outcomes of different PCTs and sickness funds, nor are there any published and unique timetables they had to stick to and hardly any regulatory principles set out formally (D). Yet, „predictability is clearly essential where firms are undertaking investment which needs to be recouped over a number of years. It means that firms can be reasonably confident that the “rules of the game” will not suddenly change, either because of a change in the overall legal and regulatory framework, or because of a change in the way that regulators behave within this framework” (Stern&Holder 1999; p.43).

4.3 Preliminary Conclusion

Measures and regulations in place to reimburse inpatient drugs are comparable in England, France and Germany. In all three of the countries, the domains listed for the reimbursement of regular drugs on one side, and, innovative or rather high-cost drugs on the other are both applied. The vast majority of drugs are part of patient classification and therefore, part of prospective hospital budgets based on case-mix. Due to a similar methodology and technical mechanisms, the funding on this type of activity is perceived comparable well within the three countries.

Also with regard to Stern and Holder’s criteria for good quality regulations the systems are comparable as can be retraced in table 5.1 below, which is a compilation of results revealed in the analysis.

Categorization by Aspect					
Country	Formal Accountability		Informal Accountability		
	Clarity of Roles and Objectives	Accountability	Participation	Transparency	Predictability
<i>Germany</i>	A	B	D	B	A
<i>England (UK)</i>	C	C	C	C	A
<i>France</i>	B	B	D	B	A

Table 4.3.1: Overall Summary of assessed Findings – Patient Classification:

Stakeholders and decision-makers encounter minor differences regarding transparency and accountability issues; however, these factors do not have a direct and sustain impact on providing and establishing a drug in the clinical practice nor on the funding of a drug. Though the sales price of a drug is often adjusted, it is entitled that patients are guaranteed access to necessary care to minimum and competitive based cost which will nevertheless allow pharmaceutical manufactures to earn a reasonable rate of return.

The clear weakness of patient classification as the base for the general financing of hospitals is a long post-production phase needed in order to update DRG, HRG or GHS-prices or rather to map new inpatient activities within the system. The therefore established supplementary and alternative measures differ significantly in their quality of regulation and with regard to decision outcomes concerning the time a drug will be able to be administered in a financially assured way in the clinical practice. On the one hand, an excellent regulatory setting, meeting all requirements of good quality regulation, defined by Stern and Holder, with beneficial decision outcomes is applied with regard to innovative drugs in France. These almost do not face any delay in their uptake after they have been reviewed on safety and effectiveness. Also prices are determined immense quick. Not as favorable the situation is concerning all other supplementary and alternative funding measures in Germany, England and France. Even though in the vast majority transparency is lacking concerning actual granting criteria, decisive factors determining the acceptability of regulation and decision-outcomes are predictability and accountability issues. These in turn depend primarily on a clear division of power according to regulatory and financial goals followed by particular stakeholders.

Categorization by Aspect					
Country	Formal Accountability		Informal Accountability		
	Clarity of Roles and Objectives	Accountability	Participation	Transparency	Predictability
<i>Germany</i>	C	C	D	C	B
<i>England (UK)</i>	C	C	D	C	D
<i>France</i>	B	C	C	A	A

Table 4.3.2: Overall Summary of assessed Findings – Supplementary Funding

With regard to regular supplementary reimbursement in France and Germany, Stern and Holder’s criteria for good quality regulation are not accomplished very well either, however, in both countries approaches are followed which are favorable in terms of administering drugs in a financially assured way.

5. DISCUSSION

The analysis of inpatient reimbursement systems revealed two different kinds of remuneration mechanisms applied to account for the need to provide drugs within the hospital setting: prospective budgets based on case-mix and supplementary or alternative funding. Both mechanisms are mutually depended and embedded in a regulatory framework (depending on the country) which more or less reflects economic priorities and social beliefs such as efforts to contain costs, competition to increase efficiency, selective contracting and bargaining in order to account for regional differences and the belief that a sufficient standard and quality of care is already established which abates the necessity to allow for an unlimited access of all possible treatment alternatives into the clinical practice. These priorities affect amongst other things the way governance elements of inpatient drug reimbursement regulations and processes are experienced and perceived by all involved parties.

The acceptability of regulatory systems is a key concern of governments, commercially operating firms such as pharmaceutical companies, regulatory agencies, patients and of course institutions associated with public service obligations, such as hospitals. On this note it was hoped to contribute to a broader societal discussion dealing with the legitimacy of regulation but also to provide decision-makers with insights in order to improve the acceptability of regulations and decision-making processes by means of exhibiting characteristics of the different inpatient reimbursement systems' regulatory frameworks and to reflect critically on their strengths and weaknesses aiming for identifying the internationally best-practice. In fact, approaching the analysis of governance elements in an internationally comparative manner proved to be reasonable for reasons which were expected in the forefront of the research but whose scope turned out to be far more extensive. Thus, the analysis often revealed critical issues regarding the 'satisfying' accomplishment of formal and informal accountability with respect to the categorization within Stern and Holder's criteria referring to "the clarity of roles and objectives", "accountability", "transparency" "participation" and "predictability", however, taking into account all notions of acceptability, i.e. not only accountability but also the quality of regulation and a common understanding of the 'rules of the game', overall the examined characteristic of the regulatory framework turned to be acceptable to everyone concerned. To substantiate this insight, an example with regard to transparency will be cited.

Providing transparency is essential as all accountability criteria discussed in that paper are interrelated and their best possible accomplishment in practice depends on each other, also "transparency will help to secure more effective participation, since firms (and consumers) will have a better understanding of the main factors which are likely to influence the regulator's decisions (as well as his overall approach). It is also important for predictability, since transparency implies that changes in regulators' approaches to key decisions will be easier to detect" (Stern&Holder 1999). On the flipside the fortification of transparency might cause the renunciation from the current priority setting and open door and gate for a broader and more detailed discussion about single drugs and therapies. Such a situation would hold both some chances and dangers. Momentarily there is a predictable time

span a manufacturer can count on to have a new product established in the clinical practice as there are predictable revenues. More transparency might lead to a situation where more manpower will be required in order to process the information and inevitably result in a more fine-meshed regulatory legal system. More transparency goes hand in hand with the need for more accountability and public discussion, what would likely change the current situation drastically. Frictions and discrepancies concerning the decision-making of the regulatory authority would be trialed increasingly in court without having the certainty of whether and when a product will be eligible to be established in the clinical practice. According to experience judicial proceedings may last over several years. Years of patent loss, revenue losses and years patients in need are denied access to possible necessary treatments.

Yet, the focus of that research was not only to explore whether regulatory frameworks ‘scrape through’ with respect to acceptability but to provide a firmer base of regulatory decision-making by means of internationally benchmarking characteristics of inpatient reimbursement systems. Information obtained from international comparative research may enable stakeholders to understand the working of their own countries’ system and to improve their regulatory frameworks and decision-making processes in terms of comprehending shortcomings and the value of maybe already accomplished regulations. Thus, an international best-practice case was presented on the example of France. In France the granting of remuneration for innovative inpatient drugs fulfills all requirements and necessities of good regulation. An exemplary separation of duties and responsibilities regarding the medical part of assessing the efficacy and the risk profile exercised by the AFSSAPS on the one hand and the price determination by the CEPS on the other hand is accomplished. The comparison of the French government elements with the one in England in Germany thereby revealed the general question whether regulatory frameworks are acceptable with respect to the accomplishment of formal and informal accountability and the quality of regulation if sponsors of healthcare are either capable of influencing regulation and processes of decision-making sustainably or if they are even in charge of stipulating regulation. Apparently, it is difficult for a (regulative) authority to stipulate a regulatory framework or measures that ensure on the one hand the provision of innovative and good quality care while dealing on the other hand with budget constraints. However, basically, only as long as regulative tasks and duties with an economic or medical character are separated from the actual healthcare financing – i.e. not just stipulated in formal documents but actually practiced separately the regulatory framework will be not influenced by daily practical constraints of single stakeholders - at least most of the time - but affect the variables above. This may be accomplished and already is successfully realized with regard to regulatory decisions in France and Germany with either considering the implementation of a semi-independent regulatory body which is working on behalf of all involved parties or by clearly separating decision-making and regulatory power according the matter of decision. The latter possibility thereby implies a unilateral limited and one dimensional scope of decision-making to one specific sector, whereas all sector-specific decisions and regulations will be

arranged with each other trans-sectorally in order to implement an overall regulation or decision without having a particular priority-driven bias. Both ways of regulatory decision-making represent acceptable approaches. Nevertheless, the maintenance of acceptability depends on a basic and superordinated requirement of good-quality regulatory frameworks: the definition of a sufficient standard basket of healthcare. Indeed, arbitrary decision-making and regulation can be avoided if the foundation pillars of a regulatory framework are set out as stringent as possible. Decision-makers should keep that in mind when stipulating regulations. But instead the study revealed a renunciation from that principle for some part. In particular with respect to the notions of accountability deficits in regulatory decision-making were discovered. In order to contain costs an intentionally forced concentration in the power of sickness funds and PCTs seems to occur. Considering the broader context three major reasons can be assumed for that kind of political motivation. The first reason concerns the attempt to avoid the stipulation of central regulations for high-cost drugs, which have not been proven to be effective in a real life setting. Thereby, the “real” need of a new drug can be estimated, from the perspective of sickness funds, without distorting the volume up-taken with explicit reimbursement decisions, which would have to go hand in hand with more transparent regulation. Secondly, sickness funds and PCTs increasingly face problems to sufficiently finance health care. Due to different patient collectives there are different individual priorities. By not enforcing PCTs and sickness funds to reason all their decisions, decisions can be made more flexible and furthermore public discussions about a critical shortage of care can be avoided for the most part. Thirdly, every drug necessary for the treatment of a patient in need is assumed to be administered by hospitals regardless its state of funding as medicines account just for a minor part of hospital expenditures. These three reasons and the underlying objectives basically explain critical issues of current regulation. Although, the tendency of deregulation in order to solve financial shortcuts in healthcare budgets is comprehensible, acceptability is suffering. Even though this approach is benefitting from a self-balancing in regulatory decision-making due to the involvement of several players with diverse interests, healthcare decision-makers would be well advised to promote a convergence of all governance elements within an overall regulatory framework for healthcare. That means, up to the present regulation is considered quite constricted with respect to one concerned sector. Thus, e.g., in Germany and France the reimbursement and funding of most medicines in the hospital setting is only dependent on hospital financing regulations. It would be worth considering establishing a tight link between hospital financing regulations concerning drugs and the broader and more extensive discussed implementation of fourth-hurdle-systems or rather the uniform application of health technology assessment methods following a clear methodology as partly accomplished in England regarding all medicines which are a matter of NICE appraisals.

While this research focused on the acceptability of regulatory frameworks with regard to notions of formal and informal accountability, Hutton and colleagues tried to provide a base to determine and improve decision making on drugs based on an internationally ‘best-practice’

comparison with respect to health technology assessment. Both approaches may be interpreted as complementary. This study attempted to discover how acceptable regulatory frameworks of funding and reimbursing inpatient drugs are and to provide an understanding of the scope of acceptability. The findings of this study directly lead to Hutton's insights, which suggest a comprehensive and permanently reflecting regulatory process of central decision-making on drugs away from an "only limited range of factors, often concentrating on clinical effects and budget impact" (Hutton et al. 2006). Both approaches are well compatible. Hutton took into account decision-making characteristics concerning the policy implementation level in order to assess all features of governance and decision-making processes regarding to the medical and economical assessment of medicines, while this study is hoped to enable the understanding of the context from a socio-scientific perspective Hutton based his framework on. Moreover, it is attempted to improve the implementation of explicit recommendations obtained from analyses based on Hutton's framework. As some questions remained dissolved "for example, is there an ideal model of the use of full HTA in reimbursement decision making, or will the best system always be determined by the health policy and health system context?" (Hutton et al. 2006) this research can help to contribute to the understanding on which notions the health system context depends on in order to ensure the acceptability for patients, firms, hospitals and governments with respect to HTAs which will be applied maybe soon also in the inpatient sector.

Moreover, the study provides a base for further research concerning regulations and decisions embedded in regulatory frameworks which govern the funding and reimbursement of inpatient drugs. A synopsis was introduced touching a multitude topics and issues which have not been sufficiently explored, yet but which would hold the chance to improve the acceptability and quality of regulatory frameworks. Thus, e.g. the relation of legitimacy and acceptability in healthcare decision making and regulation, the institutional arrangement of healthcare decision-makers within a common legal frame as well as the investigation of the actual value of formal and informal accountability criteria concerning regulatory decision-making in healthcare offer a broad scope of research objectives for the purpose of improving integrated health care decision-making on a regulatory level. Thereby, constantly, comparing individual characteristic on in an international sphere will help to obtain a more qualified and comprehensive understanding.

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APPENDICES

A1: Interview guide

Interview guide

Activity-based reimbursement of inpatient drugs by means of patient classification systems

Date of interview ____/____/____ Time of interview _____

Name of respondent _____

Position or title _____

Institution _____

Introduction

The goal in interviewing you is to gain a better understanding about several issues related to the reimbursement of inpatient drugs within the activity-based financing system (e.g. G-DRG in Germany, Tarification à l'activité in France, Payment by Results in UK) of hospitals in your country. We would like to discuss the decision making process for the development and maintenance of the activity-based financing system and stakeholders involved in that. Also we would like to discuss the funding of hospital drugs within the activity-based financing schemes as well as alternative funding measures for drugs which are excluded from the DRG-budget in Germany/HRG-budget in UK/GHS-budget in France. Also, we would like to find out what the perceptions are regarding the access to high cost drugs in hospitals. Furthermore we are interested in what barriers and opportunities there are for reimbursement of a new expensive hospital drug which cannot be paid for by the existing DRG/HRG/GHS budget that the hospital receives for treating the patient.

The results of this interview will be used to supplement and enhance the findings gained from a literature search and to establish a practical validity within the thesis. Furthermore, the purpose of the thesis is to give an updated picture of the current situation of activity-based hospital-drug funding based on the insights and information gained from this interview.

Preliminary notes

We are interested in gaining as much concrete and detailed information as possible by conducting that interview.

According our research, all of the selected experts have a certain detailed knowledge from one perspective or another. Accordingly, the questions of the interview were chosen. We are in particular interested in your specific expert knowledge. If there should be questions raised you do not feel familiar with or which you consider as not being part of your practical experience or expert knowledge, please feel free to say so in order to focus on your experience.

We tried to formulate all questions as explicit and clear as possible. However, if there should be ambiguities or equivocalities due to the general format of the questionnaire please feel free to ask for clarification any time.

I. General Questions

Activity-based hospital funding is a rather recent approach primarily targeted on performance-linked reimbursement of hospital services and cost containment.

In the UK, the introduction of Payment by Results (PbR) has changed the financial flows in the NHS, with trusts now being paid a standard national tariff for the activity they undertake in a given year on a cost per case basis. Activity is defined by Healthcare Resource Groups (HRGs).

In Germany, hospital reimbursement is based on the German Diagnosis Related Groups (G-DRG) system. Each patient is assigned to a DRG, which represents a particular group of patients having similar clinical conditions and requiring similar hospital services.

In France, a new hospital reimbursement system was introduced in 2004: Tarification à l'activité (T2A), which is a prospective payment system based on classification according to GHM (Groupe Homogène de Malades) and GHS (Groupe Homogène de Séjours).

Question 1

We are interested in learning about the current status of implementation of activity-based hospital funding.

a) *What is the current state of implementation of the activity-based funding system in hospitals?*

- _____ fully implemented
_____ implemented to some extent, but supplemented by the former financing measures
_____ not implemented, yet

Please explain.

[Transition phase already completed?]

b) *To what percentage are hospital provisions reimbursed activity-based?*

- _____ 80% -100%
_____ 50% - 79%
_____ 20% - 49%
_____ 0% - 19%

Question 2

There are a number of stakeholders involved in decisions concerning the financing of hospitals, e.g. Ministry of Health, technical institutions, hospitals, etc.

- a) *Which stakeholder is the most influential with regard to the development and maintenance of the patient classification within the activity-based funding system? Thus, which stakeholder decides about making new DRG/HRG/GHS groups and who decides about allocation of resources to particular DRGs/HRGs/GHSs?*
- b) *Could you please name the other stakeholders you consider to be important with respect to the activity-based financing system of hospitals and explain their role?*

In general, all costs for the treatment of a patient are covered by the DRG/HRG/GHS budget, which also includes drug costs. However, several high-cost drugs provided by hospitals may not be covered by the established DRG/HRG/GHS budgets of the activity-based funding schemes. Some other means to reimburse drugs outside of the DRG/HRG/GHS might exist in your country.

Question 3

- a) *How is the proportion of the budget which is assigned to the use of a drug ascertained within a patient classification group (DRG, GHM, HRG, etc.)?*
- b) *Is this part of the DRG/GHM/HRG budget adjusted to generic prices after the period the drug runs off-patent?*

Question 4

- a) *Why are some expensive drugs excluded from the DRG/HRG/GHS system?*
- b) *Based on what criteria are some (expensive) drugs excluded from the DRG/HRG/GHS?*

Question 5

- a) *What other means exist to reimburse drugs which are not included in the DRG/HRG/GHS? [E.g. Zusatzentgelte in Germany, expensive drug list in France, unbundling in the UK].*
- b) *What are the criteria for a new drug to be included in this additional funding scheme?*
- c) *Is it a temporary measure until a drug is eventually included in the DRG/HRG/GHS or other reimbursement scheme?*

II. Reimbursement of high-cost inpatient drugs

We would like to learn about the reimbursement of cost-intensive newly launched inpatient drugs which are initially not mapped in the existing activity-based funding schemes for inpatient facilities (i.e. DRG in Germany/HRG in UK/GHS in France). We are in particular interested in the process to obtain reimbursement/funding for the new high-cost medicines, either by inclusion in a DRG/HRG/GHS or by other measures.

Please imagine the following scenario:

A pharmaceutical manufacturer obtained market approval for a new hospital-only drug, e.g. an expensive new oncology medication. Because of the high price, the drug cannot be paid for by the existing DRG/HRG/GHS budget that the hospital receives to treat the patient. However, the manufacturer wants the drug to be accessible to the patient as fast as possible.

Possible solutions are:

1. The DRG/HRG/GHS for the specific indication of the drug needs to be updated. The patient group's budget could be increased by a certain amount so that the drug eventually is covered by the DRG. Another option would be the creation of a new DRG/HRG/GHS code (e.g. for a subgroup of patients) in which the costs for this new drug are included.
2. A decision is made that the new drug will not be reimbursed by the DRG/HRG/GHS to avoid too much fluctuation in the DRG budget. In this case it can be decided that the drug will be reimbursed by a funding separate from the DRG/HRG/GHS, e.g. by Zusatzentgelte in Germany, the expensive drug list (Medicament en dehors de la tarification de l'activité) in France or by reporting the drug separately in the UK.

First, I would like to talk about both of the above described solutions (decision about inclusion of new drug in DRG system or in the additional funding on top of the DRG).

Question 6

- a) *Which stakeholders are involved in the decision-making processes concerning the creation of a new patient class and the establishment of supplementary funding sources for a new drug? Is the pharmaceutical industry involved?*
- b) *Who are the stakeholders eligible and most likely to initiate an update or rather reassessment of the established activity-based funding system?*
- c) *Is a manufacturer entitled to respond or to object to a taken decision concerning his product?*
- d) *Are the decision and its reasoning published and accessible?*

Question 7

How frequent is the activity-based remuneration system updated / revised?

- *Are there any fixed dates laid down legally within which the update has to be accomplished? And if that may be the case, are the deadlines met?*
- *Or is the system only updated when this is initiated by a change in treatment practice for a specific patient population (e.g. after introduction of a new drug)? And if yes, who (which stakeholder) should initiate this?*

Question 8

Can you please describe the process to update the activity based funding system, focusing on changes in DRG-budgets and the development of new DRG-codes for a specific patient (sub-) population?

Question 9

- What criteria does a new drug need to fulfill in order to be either included in the existing DRG-budget (resulting thus in an increase in the existing budget) or to be included in a newly developed DRG specifically for that subpopulation of patients who use the new drug? [E.g. does the drug need to become standard of care, does it need to show better efficacy than existing drugs in the same indication?]*
- What are the criteria a new drug needs to fulfill in order to be included on the list of drugs for which additional reimbursement on top of the DRG is obtained (i.e. Zusatzentgelte in Germany, expensive drug list in France)? Are the criteria reasonable, transparent and accessible?*
- Does the drug's cost-effectiveness and impact upon quality of life play a role in the update process?*
- Are there any budget constraints impacting the decision-making about the reimbursement itself and the level of reimbursement of high-cost drugs? If yes, are there any opportunities to deal with these constraints?*

Question 10

In general, how much time does it take until the new drug is either included in the activity-based funding system or on the list of additional funding on top of the DRG/HRG/GHS and equally accessible to each patient in need along all hospitals?

Question 11

- Are the supplementary funding sources “immediately” accessible for the hospital after a decision was made about the kind of funding?*
- Do the new funding sources apply automatically to all the hospitals or are there any differences requiring individual hospital negotiations?*

Question 12

- a) *What would you consider as being the barriers which the manufacturer might face with regard to obtain supplementary funding and a delay in the drug's uptake?*

[What are possible means to overcome the barriers?]

Besides the system's update we are highly interested in what happens in the time between market authorization of the drug and the decision about the inclusion in the DRG or in the separate funding measure besides the DRG. From here, we would like to talk about other (temporary) means of financing which are applied in order to provide patient access (e.g. NUB in Germany) although the drug is not regularly mapped in the system.

Question 13

What measures exist to fund such a high-cost drug until it is included in the regular DRG/HRG/GHS or the list for additional reimbursement on top of the existing DRG/HRG/GHS?

Question 14

- a) *Do these measures apply immediately and automatically or are there any temporary gaps leading to a delayed uptake of the new drug?*
- b) *What is causing these gaps?*

Question 15

Who are the decision-makers involved in deciding whether a new drug will be funded by (one of these) additional measures?

Question 16

- a) *Can you describe the decision making process for the uptake of a new drug in one of these measures?*
- b) *Which criteria, instruments and mechanisms are taken into account by them in deciding about the drug's use and reimbursement?*

Question 17

- a) *What does a manufacturer has to consider in order to assure the drug's reimbursement during that period?*
- b) *Are there any specific deadlines applying?*

Question 18

For which period of time a product is eligible to be funded by means of the mentioned measures? In case the new product is not been mapped in the regular reimbursement system after that period, how will it be reimbursed until its defined inclusion to the regular system?

III. Evaluation of the activity-based funding system

Finally, we are interested in how the activity-based funding system is perceived by stakeholders.

Question 19

Do you perceive the activity-based funding system as a barrier for the uptake of new (expensive) hospital drugs?

Question 20

- a) Do you think there are sufficient opportunities in order ensure the financial coverage of a high-cost drug? Are high-cost drugs reimbursed sufficiently from your point of view?*
- b) How would you evaluate the reimbursement of very cost-intensive drugs in general?*

Question 21

How would you evaluate the transparency of the system's update?

Question 22

Did you recognize major problems in the reassessment process with respect to a quick "patient access" to high-cost drug?

Question 23

Would you evaluate the (temporary) funding measures between market approval and inclusion in the activity-based funding system as being appropriate?

THANK YOU VERY MUCH FOR YOUR PARTICIPATION!

A2: Influential Stakeholders in the different hospital remuneration systems

The regulatory framework of health care systems depends significantly on the institutions and stakeholders which are able to determine it. In particular social beliefs, economic ambitions as well as diverse priorities do impact the organization and administration but also the regulatory setting with regard to a certain level of standards in the context of accountability, transparency and further matters. Knowing that it is reasonable to shed light on the most important stakeholders involved in the explicit and direct decision-making concerning hospital financing and the reimbursement of inpatient drugs as well as on the social-political environment these stakeholders maneuver in for the purpose of enabling a holistic understanding of the problems discussed in that paper.

Germany

Many characteristics of the German health care system emerged from the conceptual design of statutory health insurance (SHI) anchored in the course of Bismarck's social legislation and developments that followed. To this day the vast majority of Germans is SHI-insured; although private insurances or rather complementary private insurances gain in importance for persons able to leave SHI or which are generally not obliged to SHI-contributions. Accordingly, health care in Germany is predominantly financed through compulsory social security contributions based on income from labor. However, private insurance expenditures are not to underestimate either, as well as tax money provided to fund investment and research costs.

The German health care system is organized in three levels, the federal government, the states and corporate bodies (Stolk et al, 2008). In contrast to most of the other health care systems the German one is historically earmarked by leaving the direct organization of health care to so called self-administrational bodies such as the association of statutory and private sickness funds, physician organizations and hospital federations. Almost all major decisions concerning the organization and administration of health care is made by these bodies on a federal and state level. That model of corporatist regulation through self-administrational bodies ensures on the one hand the governments influence with regard to the development of the overall-system by setting a regulatory framework but on the other one the direct organization and duties of administration are delegated away from the scope of the government's direct responsibility.

With regard to hospital financing the self-administrational partners consisting of the German Hospital Federation (Deutsche Krankenhausgesellschaft), the Umbrella Organization of the Statutory Health Insurance (GKV-Spitzenverband) and the Association of Private Health Insurance Companies are in charge of stipulating the G-DRG system. All system-relevant decisions concerning the organization and priorities of the G-DRG system are made by them. By their nature each of them pursuits particular interests regarding the level of funding and the DRG-system's design. While sickness funds primarily intend to contain and control costs hospitals seek to cover the costs for inpatient activities and services. Accordingly, all three umbrella organizations have to reach a consensus. "As long as hospitals and sickness funds will reach a consensus every year there won't be any dramatic problems" (Respondent 1). Although the umbrella organizations of hospitals and sickness funds are essential drivers with respect to the overall decision making their role in the actual regulation processes should not be overestimated. Thus, for instance, "due to cost increases sickness funds are unsatisfied and grumble a lot but they are not essentially involved into the regulation processes and a system change appears to be rather unlikely" (Respondent 1).

Due to the G-DRG-systems distinctive complexity and intricacy there are rather few people comprehending the entire system. Basically a very small group of persons was initiating the establishment of the G-DRG system. Some other few were more closely involved, but eventually "there are hardly 10 persons having a holistic idea of how the system works in detail" (respondent 1). At the present most of these persons hold important positions with respect to hospital controlling, administration and financing¹⁵. The system's development still relies to a big part on those persons' intellectual capacities. The limited number of experts involved, however, often led to a situation where essential overall decisions were made informally without engaging in public discussions (Respondent 1). In particular, accountability claims but also transparency and predictability issues evolve due to that situation.

The set of overall decisions is put into practice by the Institute for Hospital Reimbursement ("Institut für das Entgeltsystem im Krankenhaus – InEK"). The InEK was found in 2001 by the partners of self-administration in order to support and attend the implementation and advancement of the DRG-system in

¹⁵ E.g.:

Karl-Heinz Tuschen: Ministry of Health, Head of the Division: Economic Questions of Hospitals;

Dr. Wulf-Dietrich Leber: Umbrella Organization of the Statutory Sickness Funds, Head of Division: Hospitals;

Johann-Magnus Freiherr von Stackelberg: Umbrella Organization of the Statutory Sickness Funds: Deputy Chairman of the Board

Dr. Frank Heimig: InEK, CEO

Germany scientifically. Meanwhile the InEK is charged with the development and maintenance of the DRG-classification and the annual case-based lump sum catalog, the appliance of a rule based method, the calculation of cost-weights and the definition of additional reimbursement. Moreover, the InEK is virtually in charge of attending, supervising and controlling each single facility providing inpatient care which is being financed on an activity-cost base using patient classification systems (Respondent 3, HOPE 2006, Vereinbarung über die Einführung eines pauschalierenden Entgeltsystems §3; KHG § 17b para. 2&3; InEK 2007, 2008, 2009). The InEK is “basically constructed like a monopole regulation authority as can be found in other areas such as gas, water electricity and public transport businesses. Due to the background of the InEK’s intellectual capacities it generates a multitude of ideas with regard to the system’s improvement itself and exercises “informally” a lot of responsibilities even though it was not thought to do so initially. Beyond any doubt the InEK has advanced to “the most important stakeholder” with respect to G-DRG-system (Respondent 1&3). It distinguishes itself by a highly pragmatic, efficient and solution-oriented work which it was awarded for by all interviewed experts. In fact it seems like the InEK accomplishes the challenging task to find solutions which are satisfying for all stakeholders, for instance regarding the exclusion of high-cost drugs from activity-based reimbursement. These solutions allow hospitals to be reimbursed with reasonable revenues to provide all care necessary, but do not stress the budget of sickness funds out of scale and which allow manufacturers to earn a reasonable rate of return. That is remarkable taking into account that the InEK can be approached officially just by hospitals and sickness funds but not by any other stakeholders. Moreover, basically decisions made by the InEK cannot be questioned legally but the institute can be held accountable merely by the partners of self-administration. That is likely the case because of the methodological approach the InEK is following in calculating DRGs but also due to the fact that the InEK is not primarily in charge of allocating hospital budgets or negotiating prices.

That in turn redounds upon sickness fund associations and single health insurers. Although these payers are informally urged to follow advises given by the InEK their space for maneuvers keeps considerable. In particular with regard to funding decisions concerning certain high cost drugs regulations can be quite arbitrary as will be explained further below. Sickness funds need to compile with federal-wide agreements accomplished by the federal joint committee, where also hospitals, physicians and patients are represented, however due to their high degree of organization health policy agreements and priorities are significantly influenced by the payers’ point of view. The implementations and exercising of rules and their decision-making does not necessarily has to be uniform or transparent.

To sum up, in terms of who is in charge of the priority setting and decision-making hospital funding composes of two main stakeholders. The InEK and sickness funds, whereas the InEK is in charge of regulating and administering the system based on guidelines constituted by the partners of self-administration. It nevertheless comprises of significant power and can influence the system sustainable. Sickness funds are in charge of all formal decisions related to particular funding matters. Further examination of the regulatory setting and the power resources of involved stakeholders will provide insight in the decision-making system and its impacts in practice.

England (UK)

For more than 50 years health care in England almost entirely happens through and within the National Health Service (NHS). When the NHS was founded in 1948 it was aimed to provide every human being in England to be given necessary access to health care irrespective the socio-economic status.

Overall, health care in England is tax-funded. More than 70% of the national health care budget is generated through tax-revenues, 20% through social contributions and merely 5% result from other contributions (DH 2010). For a long time the English health care system, the so called Beveridge-system, was perceived internationally as the ideal type of a publically controlled and financed health care service. However, since recently, the integrated system of public finance-planning and public provision of health care services is subject a transition process towards regulated health care markets. Thus, there is the opportunity for private insurance an increasing number of citizens tends to follow.

The health care budget’s allowance to health care providers within the NHS follows a multilevel system of central planning, local allocation and competition (Talbot-Smith et al. 2006). Thereby, the Department of Health (DH) and the Department of Finance negotiate a health care budget for three years, which is subsequently allocated to local and regional health care providers, based on a stipulated formula. Current expenditures are transferred to the 152 primary care trusts (PCT) which are in charge of ensuring health care.

In fact, the DH and PCTs are the single most important stakeholders within the NHS comprising of significant influence and decision-making power whereas the DH is providing a general direction and a regulatory framework for budget and health care provision-related decisions made by PCTs. Also with regard to the financing of hospitals the DH is in charge of setting regulatory policies. But furthermore, it just does not determine the direction of regulatory policies but fulfills almost all regulatory tasks of practical concern regarding the patient classification and the overall determination of the prospective inpatient budget based on case-mix. Although, the DH does not appears to be the driving decision-maker with regard to activity-based hospital funding it comprises of an immense influence (Respondent 11). Hence, even though HRGs are determined by clinicians and expert working groups from the entire NHS, the DH eventually decides about how

HRG-prices are determined, what priorities are followed and how budgets are allocated (Respondent 11). There are several participants involved in these decisions and tasks within the DH; however the driving force comprising of sufficient know-how is the NHS-Information Center, which is part of the DH. The DH is also in charge of excluding drugs from the inclusion of prospective budgets based on case-mix. Considering the way budget regulations are set in general (will be explained below), the DH is making decisions rather transparent. That might be due to the fact, that finally the DH will be the major stakeholder, which is hold accountable for regulatory decisions. As the DH is involved in each single decision concerning regular inpatient-financing decisions, there is an inherent need to the DH to fulfill certain accountability standards. By publishing statistical reports, surveys, annual final reports and press releases the DH tries to meet the public demand for accountability and transparency (Höhndorf 2002).

The actual allocation of hospital budgets as well as the decision making regarding certain priorities and single-case-decision-making is incumbent to primary care trusts (PCT). There are about 152 PCTs whereas each one is covering a separate local area. PCTs are maybe the most decisive stakeholder with respect to the coverage and quality of health care provided, thus, they fulfill not merely a regulatory task but are also in charge of financing health care services. In fact, PCTs administer and decide about approximately 80% of the total NHS budget and thereby pose the most crucial instance to patients, health care providers and pharmaceutical manufacturers. PCTs decide about the range of health services provided by hospitals and ought to ensure the accessibility of health care services to patients in need. Regarding the reimbursement and funding of drugs in the hospital setting but also in general PCTs comprise of special committees responsible for decision-making on drug's eligibility to be administered in the clinical practice. These groups are often referred to as Drug and Therapeutics Committees. Based on budget considerations these committees attempt to rationalize and limit expenditures caused by the administration of drugs in the hospital. Generally, these committees take responsibility for decisions on new drugs but also review the use of approved and already established drugs. By using health technology assessment methods, decisions are tried to be substantiated scientifically in order to influence hospitals' formularies of drugs identified to be necessary to meet the clinical needs of patients. Although hospitals are able to define their very own and individual formularies, decisions made by Drug and Therapeutics Committees on the value and necessity of drugs often result in the rejection of PCTs to fund drugs aimed to administer in the hospital. As a matter of fact, PCT are anxious to generate public acceptance for their decisions, however they are virtually independent in making funding decisions concerning drugs and tend to outweigh their local health economy budgets with the rejection of high-cost-drugs (Respondents 12 + 13 + 14).

There is however, one exception or rather restriction to PCTs concerning the extent of decision-making power. This exception is due to the National Institute of Clinical Excellence (NICE) which issues appraisals on the use of new and already established drugs within the NHS. NICE is an independent organization that was originally set-up to defuse the so called post-code lottery in healthcare decision-making of PCTs. By assessing medicines, treatments and procedures according a clear evidence-based methodology a common standard of supplying health care was aimed to be accomplished among PCTs. NICE appraisals primarily base on efficacy and cost-effectiveness considerations, i.e. NICE is determining the cost-benefit boundaries in order to make recommendations to the NHS, which are obligatory and thought to be followed by each PCT (NICE 2010). Hence, even though NICE is not directly involved in regulating or deciding about hospital funding its decisions on drugs, treatments and procedures impacts the decision-making of PCTs and the provision of care in hospitals directly as all stakeholders within the NHS are urged to follow recommendations given by NICE.

To sum it up, in terms of making essential decisions regarding the reimbursement and funding of medicines in the hospital practice, there is only one decisive stakeholder – Primary Care Trusts. In fact these are asked to follow advices and recommendations issued by the DH and NICE, but their space for maneuver remains big and just in the very least cases a PCT will be urged to surrender its decision-making power as the analysis in sections 3.3 and 3.4 will show.

France

Traditionally health care in France is organized state-centered whereas the government and the parliament have an influential role in the way health care is steered. The public health insurance system was implemented in 1945 and is divided in three main schemes: a) general health insurance („Régime générale d'assurance maladie“) b) an insurance for particular occupational groups such as artists, agriculturists and self-employed business men and c) a basic insurance coverage for students and unemployed persons („Couverture maladie universelle“) whereas the vast majority of employees is covered by the general scheme which is funded primarily through compulsory social security contributions and taxes particularly collected to fund health care. In addition, almost every insured person is subscribed to a complementary private health insurance on a voluntary basis. Patients with low income are eligible to be covered by the complementary universal insurance coverage in order to meet the three main principles of French health insurance: 1) equal access to health care for all citizens regardless the place of residence and income 2) quality of treatment and 3) solidarity. Thereby France comprises of pluralistic health care provision structures where public, semi-public as well as private providers provide health care services side-by-side and patients are allowed to freely choose the physicians and hospitals they want to be treated by.

Due to the involvement of numerous actors consigned with the organization and administration of health care provision and financing the French health care system is relatively complex. With regard to the financing of hospital care several stakeholders are involved in decision-making processes. Yet, a clear division of responsibilities and duties characterizes the organization of authorities engaged with regulatory processes and the administrative maintenance of the hospital financing system and the pharmaceutical system. A complex interaction of AFSSAPS (Agence française de sécurité sanitaire des produits de santé), CEPS (Comité économique des produits de santé), and transparency commission, LEEM (Les Entreprises du médicament), ARHs (l'Agence Régionale de l'Hospitalisation), ATIH (Agence Technique de l'Information sur l'Hospitalisation) and UNCAM (l'Union nationale des caisses d'assurance maladie) can be observed regarding the assignment of particular decisions. Nevertheless the complex distribution of decision-making powers, administrative ways as well as the distribution of decision-making powers appears to be transparent and in harmony with each other (Respondents 7 & 8). That situation is likely due to the Ministry's coordination under whose umbrella all decisions take place.

In general the French Ministre de la Santé et des Sports (Ministry of Health = MoH) is the driving force and the overall planning and legislative authority in the field of pharmaceutical and inpatient policies. Basic guidelines, legislations and principles are enacted and established by the MoH. These serve as the base for pricing and reimbursement decisions concerning inpatient activities and pharmaceutical products. Specific funds on top of a hospital budget are granted and allocated directly by the Ministry. The MoH is in charge of approving the use of drugs for a particular care setting, i.e. whether a drug should be used in primary care or in the hospital setting and eventually decides whether a drug obtains the status "reimbursable" (Sandier et al. 2004). As a matter of fact the MoH can be identified as the center of decision-making. Although, it was attempted to decentralize the distribution of decision-making power further, including also system-relevant decisions, "everything is done by the Ministry of Health (Respondents 8 & 9).

The MoH in turn, is supported by so called arm-length bodies working on behalf of it. With respect to all technical matters concerning the classification of inpatient activities l'Agence Technique de l'Information Hospitalière (Technical Hospitalization Agency = ATIH) acts as the most important stakeholder. The ATIH was founded in 2000 to "develop, maintain and update" (Durand-Zaleski 2008) the French system of activity-based hospital financing. Basically, the ATIH is in charge of everything related to the classification of patients. It is operating the annual cost- and activity data collection and thus checks whether all sample hospitals fulfill the required cost-accounting standards; it performs the data examination and finally calculates the tariffs. Due to its positioning and duties in the health care system it is directly bounded to the instructions and orders of the MoH. Thus, even though it is thought to act rather independently it finally will follow the Ministry's direction and works on behalf of it (Respondent 7). Consequently, for all made decisions the MoH has to be held accountable. However, since the ATIH has to be considered as a primarily administrative body which is regulating and applying the methodology to classify patients its decision-making will be of less impact than the one of CEBS and transparency commission.

In France, the Economic Committee for Health Care Products (CEPS) is responsible for the decision-making and setting price activities. The CEPS fits within the state-centered steering which requires that prices of in particular expensive reimbursable drugs are regulated on the national level. The CEPS brings together representatives from the Ministry of Economy and Finance, the Ministry of Industry, the Ministry of Health, national sickness insurance organizations and the National Union of Supplementary Insurance Organizations, the Directorate of Hospitals in the Ministry of Social Affairs and the Ministry of Research. The CEPS is asked to regulate the conditions under which a drug will be used and stipulates an agreement with pharmaceutical companies about the proper use, rebates and sales volumes of their products (Becquart et al. 2008). Furthermore, the CEPS negotiates with pharmaceutical manufacturers prices of drugs. The level of participation a manufacturer is eligible to, however, is rather limited. A manufacturer may represent and defend its product's value but in case an agreement between the manufacturer and the CEPS cannot be reached the drug's price can be set by the CEPS, which is emphasizing the broad scope of competences the CEPS comprises of. Taking into account the CEPS' responsibilities and decision-making powers it evidently plays a significant role with regard to its standing in price negotiations with a manufacturer. Even though decisions made by the CEPS can be challenged legally by a manufacturer on two jurisdictional levels the influence of CEPS should not be underestimated. Decisions made by the CEPS maybe cause one of the most extensive impacts upon the revenues a manufacturer wishes to gain with the marketing of a product. In its decision-making the CEPS relies among other things on the advice of the transparency commission.

Since 2004, the transparency commission has been part of the Haute Autorité de Santé (French National Authority for Health = HAS). The commission comprises of independent experts such as general practitioners, medical specialists, methodologists, epidemiological experts and pharmacists. Its main purpose consists of scientific advisory with regard to a drug's position in the treatment strategy on the basis "of two indicators, the medical benefit (SMR) and improvement in medical benefit (ASMR) compared with existing treatments" (Grandfils 2008). Moreover the transparency commission gets involved in the evaluation of a drug's eligibility to be included on the list of reimbursable drugs as well as in the review of the reimbursable drugs list. The commission bases its advices mainly on data submitted by manufacturers and existing literature. It also advises

the MoH on the classification of drugs with respect to the care setting a drug should be used in and the stakeholders eligible to purchase the drug. The transparency commission seems to be the only body without actual executive authority, yet still exercises big influence on the decision-making by means of scientific advisory. By the nature of science most of the arguments provided by the transparency commission should be well reasoned and publicly accessible.

Another decisive role is played by the French Agency for the health safety of health products (AFSSAPS) which in general is in charge of granting marketing approvals for new drugs based on medical evidence. However, the AFSSAPS plays a further important role concerning the uptake and funding of drugs which do not benefit from a marketing approval or which are supposed to be used in an off-label practice, as will be explained in section 3.4.1.3.

To sum up, there are two important stakeholders having a decisive influence with regard to the priority setting and the decision-making concerning hospital funding: the Ministry of health and the CEPS. While the MoH is in charge of regulating and administering all sub-systems related to the funding of hospitals and pharmaceuticals the CEPS is the actual authority with respect to the price a manufacturer will be able to ask for a product. Both stakeholders are essential considering the uptake and funding of a drug. Likewise both stakeholders meet to a sufficient degree the requirements of transparency, predictability and accountability but do not allow in an adequately manner for participation of other stakeholders as will be shown in the further course of that study.

A3: Defining case-group prices

Step 1: “Collection of Cost- and Activity Data”

The term data sample is used to describe the number of hospitals from which reliable cost data is collected and pooled (Schreyoegg 2006). With regard to the size of a data sample a clear trade-off between representativeness and high-quality data standards can be ascertained. The size of the data sample depends to a large extent on the priority assigned to the goals of quality and representativeness as well as on the particular cost accounting systems, the hospital ownership and the position of the regulating authority in the health care system (Schreyoegg 2006; Lungen&Lapsley 2003). Basically, there are two approaches, with respect to France, Germany and England (UK) of how cost and activity data is gathered: a) France and Germany emphasize data quality, i.e. cost- and activity data is collected in just a small number of selected hospitals whereas b) in England each hospital is urged to provide cost- and activity data in order to ensure the highest possible level of representativeness.

Step 2: “Cost-Price-Calculations”

In calculating DRG/HRG/GHS cost-prices the major problem is to determine medically meaningful and coherent groups of patients with a comparable use of resources or rather homogenous costs based on the collected reference activity and cost data. Therefore each country is applying an individual more or less consistent methodological approach. While the InEK and the ATIH are following strict methodological approaches that are publicly accessible to everyone¹⁶ it is striking that in England significant decisions in the costing process are not based on a strict and publicly accessible approach but are made by permanently changing working groups derived from empirical estimations.

In France and Germany “all things that appear during a treatment are incorporated into the average considerations, i.e. if only every 10th patient gets a drug, just 1/10 of drug will be considered in a DRG. [...] The system is constructed regardless the drug’s price [...] in the moment a product is used in the hospital practice it will be considered automatically [...] without any reservations” (Respondent 4).

Step 3: Definition of Case-Group-Prices

In a last stage prices per product / case group have to be defined. That can be done directly if the average costs per HRG/GHS have been calculated and prices for each HRG/GHS are set accordingly, like it is the case in England (UK) and France (Bellanger&Tardif 2006; Epstein&Mason 2006). However, most tariffs will not be in accordance with the costs estimated due to secondary adjustments. These however, as it is the case in both England and France, are explained just sporadically (usually based on single examples) and are influenced by certain priorities such as the attempt to increase the hospital’s level of reservation when administering drugs in terms of cost-containment efforts. Thus e.g., in France “it’s a nightmare to split DRGs and the other nightmare is to increase the hospital budget. The best thing is if a drug can be included in an existing DRG price” (Respondent 8). Even though knowing the priorities makes decisions more predictable the outcomes are less favorable. In England most of the adjustments are applied more or less intuitively without a comprehensive reasoning of how particular values were estimated (Respondent 12 + 13 +14). In fact there is a final document explaining all accomplished changes, but due to the fact that changes are often based on the opinion of a small group of experts transparency is lacking. This also means that issues like HRG-splits or the increase/decrease of the monetary value of an HRG can be ascribed logically; however, no official reasoning is done. This in turn constrains the possibility to challenge made decisions legally in a well substantiated and effective way. Furthermore, it appears to be impossible to clearly appoint stakeholders who finally make decisions or to retrace the reasoning of the decision-making on e.g. case group splits or rather the assignment of cost-parameters to particular case-groups. Thus, there is a clear lack of accountability, transparency and the clarity of roles necessary in order to challenge decisions or to engage in a public discussion for the good of the PbR-system and for the sake of a patient’s well-being (Respondent 10). The way HRG and GHS budgets currently are derived is broadly perceived as being very difficult due to its technical complexity. Even though the “Department of Health would say it’s a great system which is very transparent [...] it is almost impossible to get to the bottom of any decision-making process” (Respondent 13).

In contrast to France and England, Germany is applying cost weights “which define a relationship between treatment episodes according to the intensity of resources used” (Schreyoegg et al. 2006) in order to meet regional differences. Cost weights have the advantage that merely the price of the DRG with the cost weight of “1” has to be set or negotiated, what makes the system generally more predictable. All other DRG prices may be derived automatically by multiplying the DRG cost weight attached to each DRG with the price set for the DRG with the cost weight of “1” (Ankjær-Jensen et al. 2006). Thereby prices for a single product will be less biased and it is more difficult to influence them according to certain priorities such as the undervaluation

¹⁶ http://www.g-drg.de/cms/index.php/inek_site_de/Kalkulation/Kalkulationshandbuch

of particular case groups. That means, by intentionally pricing a case-group lower than the costs accruing with the provision of a procedure (which is mapped in this case-group), hospitals might tend to avoid providing this certain procedure as the provided activity is not being financed sufficiently with the revenues gained from the case-group's price.

The indicative DRG with the cost weight of 1, the so called state-wide base rate, may differ among the different federal states (Länder) in Germany. It is a matter of negotiations among the state hospital associations and statutory sickness funds. The state-wide base-rates in 2009 were ranging from €2775.00 in Sachsen-Anhalt to €3008.08 in Rheinland-Pfalz (cf. AOK 2009).

A 'migration-table'¹⁷ comprises of all DRG-splits, DRG consolidations, etc. in order to be able to retrace all changes. A semi-public reasoning is attempted with the publication of an annual 'final report'¹⁸. The provision of a holistic understanding, however, fails to appear and is not wanted either as it would enable the opportunity for lawsuits (Respondent 1 + 3). In fact the decision-making process itself as well as the publication of the InEK's reasoning with regard to the made decisions appears to be a "two-edged sword". None of the interviewed experts was evaluating the decision-making process as being very transparent. Yet, hospital- and sickness fund associations seem to agree strongly with that way of decision-making. Merely, the Association of Research-based Pharmaceutical Companies was publishing in 2006 a position paper which argued for more transparency in the decision-making process and a detailed reasoning with regard to the made decisions (vfa 2006). However, there are influential voices within the industry itself that are highly in favor of how decisions are made. The interviewed industry expert emphasized the "extreme pharma-amiability" of the G-DRG-system and noted that "increased possibilities for law-suits would not make the system more favorable [for a pharmaceutical manufacturer] but prolong the decision-making processes tremendously".

Overall, the price-setting procedure in all countries is influenced by certain political priorities and cost-considerations that influence technical implementations to some degree. Subsequently, accountability and transparency issues arise due to absence of a comprehensive reasoning how decisions were made as these ones would provide the opportunity for a broad societal discourse.

¹⁷ http://www.g-drg.de/cms/index.php/inek_site_de/G-DRG-System_2009/Fallpauschalen-Katalog/Migrationstabelle

¹⁸ http://www.g-drg.de/cms/index.php/inek_site_de/G-DRG-System_2009/Abschlussbericht_zur_Weiterentwicklung_des_G-DRG-Systems_und_Report-Browser

A4: Opportunities for Spontaneous and Unscheduled Updates

Due to the way of how calculation- and updating-processes of patient classification systems are organized in all of the countries there are barely opportunities for spontaneous and unscheduled re-assessments and updates. Basically there are two possibilities of incorporating spontaneous changes which are not based on statistically significant data within the system. The first possibility refers to the institutions in charge of the case-payment calculations which would have to make foresights of how prices are going to change (Respondent 1). That would be practicably feasible but tremendously labor-intensive and “the accuracy of the tariff would depend on the accuracy of [...] assumptions” (Green & Baird 2006). The second possibility relates to the opportunity to adjust single tariffs on the base of individual suggestions from the practice as done in England by the Payment by Results Clinical Advisory Panel. The review decision on whether any adjustments are required, however, represents in most case a “mockery” (Respondent 8). In fact, that opportunity is a consequence of the peculiar position of the National Institute for Clinical Excellence and the obligation to provide sufficient funding within three months for products appraised positively by NICE.¹⁹ Furthermore, the problem arises that PCTs do not automatically pass forward the additional funding to the individual trusts but ask the single hospital to provide explicit evidence that the net additional costs of all in-year NICE guidance²⁰ exceed the total allowances made for that provider, i.e. PCTs a priori assume also drugs positively appraised by NICE to be included in the regular hospital budget until the hospital proved the opposite. As a matter of fact the uptake and administration of in particular cost-intensive drugs will be consequently semi-explicitly constrained because hospitals firstly have to prove a shortage of funding and secondly they cannot be sure their argumentation will be accepted by PCTs. Moreover, net additional costs for all new in-year NICE guidance will be calculated as new acquisition costs only deducted by the amount of drug costs which are expected to be displaced by the new NICE guidance.

With regard to issues of participation a direct and indirect way of stakeholder-involvement can be observed. In general it may be observed that in Germany and France in particular medical-specialized organizations, self-administrational bodies in the area of stationary care, federal associations of physicians, umbrella organizations of medical device manufacturers, umbrella organizations of pharmaceutical manufacturers and further organizations and institutions are asked to submit suggestions for modification and improvement. Even the submission of specific suggestions concerning DRG/GHS-splits, the exclusion of drugs from the activity-based funding or the increase of a case-payment is no peculiarity. The adoption and handling of these suggestions, however, is solely incumbent on the InEK and the ATIH. Both are not obliged to deal with submitted suggestions, nor do they have to justify their decision-making or have to reason the way decisions were made.

In England, in contrast, the direct participation of stakeholders from the clinical practice, from universities and PCTs is required to some extent. Although there are certain groups dealing with the overall system within the department of health the engagement of further stakeholder is quite distinctive. Their direct influence on the price-setting activities, however, can be assumed to be rather small as there are certain dominating priorities with regard to cost containment efforts (DH 2003; Respondent 13).

¹⁹ Cf.: “NHS Constitution” published on January 21, 2009

²⁰ New drugs and technologies that are subject to NICE guidance in-year

A5: Impact of NICE TAGs on PTPs

NICE Technology Appraisal Guidances do have an impact upon the entitlement and the level of reimbursement for drugs and medical devices. That also applies to new drugs which are being financed to some extent by 'pass through' payments. According to the most recent NHS constitution published on January 21, 2009, all PCTs are obliged to make funding available within 3 months of the NICE TAG publication. After a NICE TAG is being released usually all previous funding arrangements cease and are being reviewed or rather revised in line with the NICE guidance. Where PTPs were agreed on in advance of a NICE TAG the same rules apply for them as for mandatory tariffs examined above. NICE usually publishes its recommendations in the last week of each month. Thus, if there were any PTP in place for a drug which NICE was assessing in November 29, 2009, PCTs are virtually not allowed to exceed the implementation of the NICE TAG by 3 month. Subsequently, the PCT would have to provide 'regular' reimbursement or rather adjust the mandatory and non-mandatory budgets by March 1st, 2010, i.e. from there on the drug would be remunerated for solely by means of mandatory and non-mandatory tariffs but the PTP does not apply anymore. That procedure might be a chance for new drugs - considered by NICE as being priorities - to overcome the uncertainty of arbitrary PTP funding mechanisms. The priority-setting in the topic selection process may be influenced by the manufacturer just partly. While clinicians and the general public do have the chance to submit suggestions to NICE directly, a manufacturer is urged to submit its suggestions to the National Horizon Scanning Centre which will notify the Advisory Committee for Topic Selection (NICE Guide for Manufacturers and Sponsors 2004). This committee will set the priorities based on selection criteria developed by the DH in 2006:

- burden of disease (population affected, morbidity, mortality)
- resource impact (i.e. the cost impact on the NHS or the public sector)
- policy importance (i.e. whether the topic falls within a government priority area)
- whether there is inappropriate variation in practice across the country
- factors affecting the timeliness or urgency for guidance to be produced. (DH July 2006).

In the appraisal process itself the manufacturer should make sure that all the relevant data is taken into account, should provide all necessary data (where appropriate) and comment or rather engage in public discussion about the interpretation of evidence based and published documents.