


The German Pharmaceutical Market:

Perspectives after the Federal Elections of 2005

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Princeton, New Jersey – October 18, 2005

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OVERVIEW

Purpose: to provide some background information on current pharmaceutical politics in Germany

- ↪ **GMG 2003 – The Latest Reform**
 - ↪ Market Situation *before the GMG*
 - ↪ Political Debate
 - ↪ Political Consensus
- ↪ **Federal Elections 2005**
 - ↪ Health Politics: *Focus on Financing Models*
 - ↪ Market Situation *after the GMG*
- ↪ **Some Political Perspectives**

2 Pharmaceutical Politics in Germany 2005 Princeton, NJ - Oct. 18, 2005 after the federal election of September 18 

“I always avoid prophesying beforehand, because it is much ...



... better policy to prophesy after the event has already taken place.”

Winston Churchill 

INTRODUCTION

My usual disclaimer: **Health Economics**
should **not** be confused with health care policy, politics, or even cost containment.



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IV

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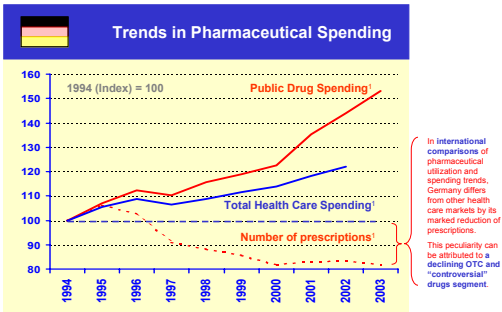
GERMAN HEALTH CARE MODERNIZATION ACT (GMG) 2004

- ↳ Market development before enactment of GMG
- ↳ Political debate
- ↳ New pharmaceutical regulations enacted with GMG

IV

BACKGROUND

Since 1995, the prescription drugs bill had risen faster than total health care spending.
Pharmaceuticals are perceived to contribute to the financial crisis of health care systems.



Sources: BMG, Arbeits- und Sozialstatistik, Schwabe und Puffrath 1995 - 2004, all data ("public") refer to statutory sick funds (GKV)

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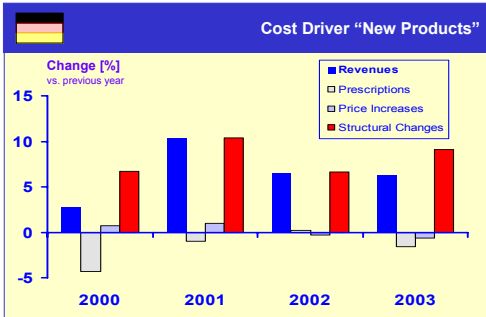
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IV

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BACKGROUND

In line with the dynamics of other European pharmaceutical markets, new products had been the dominant growth driver in Germany.



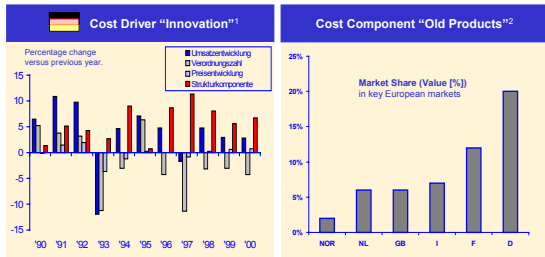
Public sector (statutory sick funds, GKV) retail prescription drug spending; data source: Schwabe and Pfaffath 2001, 2002, 2003, 2004
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BACKGROUND

Prescription drug spending analysis – market situation in 2000

An Emerging Challenge: "Financing Innovation" (1990-2000)



Component analysis by U. Schwabe und D. Pfaffath (1991-2001);
 "structural effect": corporate changes within and between individual products ("Inter- and Intrafirmamententfäcke");
 Definition of "old product": launched > 40 years ago; source: IMS (1998-2001)
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BACKGROUND

Recent population surveys in Germany

Pharmaceuticals: Public Perceptions

- Drug prices are too high **89%**¹
 - Patient co-payments should not be increased **87%**² – **88%**⁴
 - Sick funds should control drug prices **88%**³
 - Sick funds should provide information about benefits of new treatments and of new drugs **76%**³ / **73%**³
 - Industry profitability should be reduced **55%**¹
 - Opting for drug lists (if premiums reduced) **47%**² – **56%**^{3*} (**65%**^{3**})
 - Supporting a positive list for drugs **29-43%**¹
- Willingness to pay for guaranteed access to innovations **60%**²

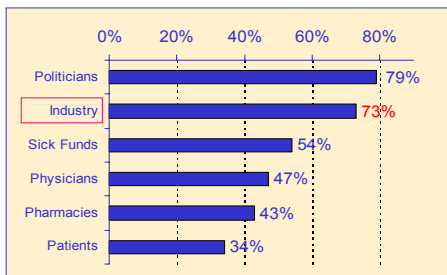
*respective of reduced premiums; **Drugs should be paid for by sick funds only if and when their use is efficacious and appropriate.
 Janssen-Cilag Population Study 1996; Janssen-Cilag Population Study 2002;
 WfLÖ-GKV-Monitor 1998/99; WfLÖ-GKV-Monitor 2002
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BACKGROUND

Recent population surveys in Germany

Responsibility for Financial Crisis¹



¹Janssen-Cilag Population Study 1998

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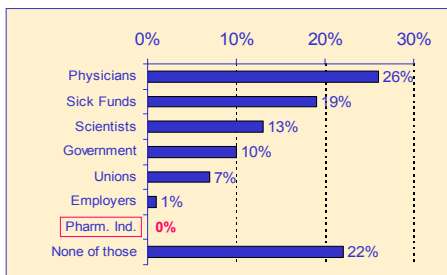
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BACKGROUND

Recent population surveys in Germany

Trust in Patients' Agents¹



¹Janssen-Cilag Population Study 2002; according to the same survey, 78% of respondents wish institutionalized public participation such as a "Citizens Council"

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BACKGROUND

Recent population surveys in Germany

Selected Public Perceptions

Cost containment

→ Very limited public support for the political focus on cost-containment ("Beitragssatzstabilität").

Pharmaceutical products

→ "Drug prices should be controlled."

→ The public rejects increased cost-sharing on drugs.

→ There is a strong public preference (and willingness-to-pay) for access to innovations.

Pharmaceutical industry

→ The pharmaceutical industry is believed to contribute to the financial crisis of the health care system. "Drugs are part of health care – the pharmaceutical industry is not."¹

¹Heinz Redwood

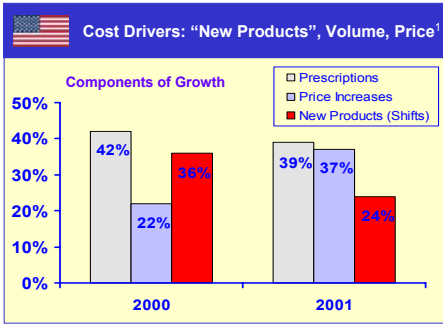
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BACKGROUND

Components of growth in U.S. prescription drug spending as an indicator of pharmaceutical market dynamics in the absence of regulation



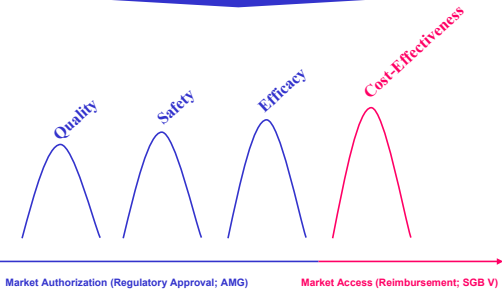
¹Data source: American Institute for Research (AIR) analyses of Scott-Levin data, reported by National Institute for Health Care Management (NIHCM) 2001, 2002



BACKGROUND

The Political Debate

The Infamous "Fourth Hurdle"



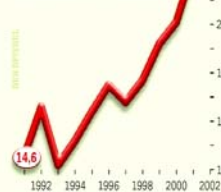
POLITICAL DEBATE IN GERMANY

Focus on pharmaceutical spending



"Jäger der Patent-Milliarden"¹

Arzneimittelausgaben
der gesetzlichen Kranken-
versicherung in Milliarden Euro



Die Pharma-Weltweiter...
Arzneimittelumsatz 2003 in Mrd. Euro

Land	Umsatz
USA	28,4
Japan	18,8
Frankreich	11,8
Italien	10,8
Deutschland	10,8
UK	10,8
China	10,8
Indien	10,8
Brasilien	10,8
Russland	10,8
Indonesien	10,8
Südkorea	10,8
Argentinien	10,8
Chile	10,8
Peru	10,8
Colombien	10,8
Venezuela	10,8
Ägypten	10,8
Marokko	10,8
Algerien	10,8
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Syrien	10,8
Jordanien	10,8
Irak	10,8
Saudi Arabien	10,8
UAE	10,8
Qatar	10,8
Katar	10,8
Oman	10,8
Yemen	10,8
Sudan	10,8
Ethiopien	10,8
Somalia	10,8
Kenya	10,8
Uganda	10,8
Rwanda	10,8
Burundi	10,8
Madagaskar	10,8
Malawi	10,8
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Botswana	10,8
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Angola	10,8
Guinea-Bissau	10,8
Sierra Leone	10,8
Liberia	10,8
Ivorküste	10,8
Ghana	10,8
Senegal	10,8
Gambia	10,8
Guinea	10,8
Äquatorialguinea	10,8
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Kamerun	10,8
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Sudan	10,8
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Gesundes Sparpotenzial
Eine amerikanische Langzeitstudie mit über 40000 Probanden zeigt, dass die endokrinen, Hochdruck senkenden Medikamente in den meisten Fällen nicht besser wirken als das Unkrautmittel Oxibutolol. Übertragen auf Deutschland, ergibt sich eine mögliche Kostenersparnis in Milliardenhöhe.

In Deutschland:

- binden etwa 20 Mio. Menschen unter Hochdruck
- werden rund 10 Mio. Personen unentgeltlich behandelt
- profitieren im Jahr 2003 ca. 5 Mio. Patienten eine Monotherapie mit mindestens 100mg Oxibutolol

Eine Ersatztherapie mit Kostenvorteil war möglich für:

Anteil	Personen	Kosten
75% der ACE-Hemmer	1158 Mio. €	
80% der Calcium-Antagonisten	587 Mio. €	
20% der Diuretika	77 Mio. €	
Gesamt	1822 Mio. €	
Kosten für die Ersatztherapie mit Oxibutolol	379 Mio. €	
Sparpotenzial:	1423 Mio. €	

Quelle: Deutscher Bund der Arzneimittelhersteller, Berlin

... und die deutsche Liga
Arzneimittelumsatz 2003 in Mrd. Euro

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POLITICAL DEBATE IN GERMANY

Focus on pharmaceutical spending (Germany, summer 2003)

Politicians and Their Consultants



→ „**Patentgeschützte** Arzneimittel mit pharmakologisch-therapeutisch vergleichbaren Wirkstoffen ... werden künftig in die Festbetragsregelung einbezogen.“¹
→ „Zur Steuerung des **Verordnungsverhaltens** werden künftig **Honorare und veranlaßte Leistungen (Arzneimittel, Heilmittel)** miteinander verknüpft.“¹



→ „Für die Erstattung von **neuen Arzneimitteln** sollte deren ... Kosten-Nutzen-Verhältnis bestimmt werden.“²
→ „Wir müssen an die **hohen Pharmakosten** ran – ohne das wird die Gesundheitsreform auf Dauer nicht gelingen.“³



→ „Die massive Steigerung der **Arzneimittelausgaben** ist „nicht allein medizinisch gerechtfertigt.“³
→ „Die Industrie ist mit ihrem **Freiraum bei der Preisgestaltung** nicht immer verantwortlich umgegangen.“³

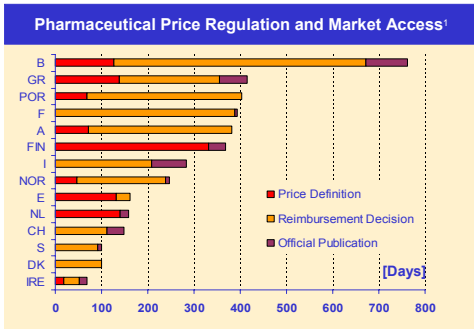
¹BMGS, „Komprimierte Fassung ... eines Gesetzes zur Modernisierung des Gesundheitssystems ...“, May 8, 2003;
²Gleitsch G., Herrmann C., Lauterbach K.W., Schweser P., Wismar J., „GKV-Reform 2003 – Reformen für die Zukunft“, Fv-Eltern-Stiftung, August 2002;
³K. Lauterbach, quote from Der Spiegel 14/2003 (11.03.2003).

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BACKGROUND

Pharmaceutical price regulation:
impact on market access of a “fourth hurdle”



¹Data: Cambridge Pharma Consultancy (2002)

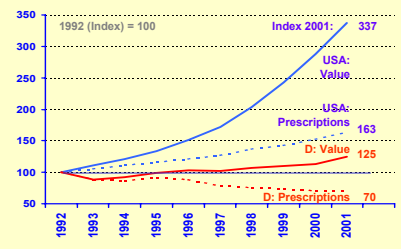
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BACKGROUND

Escalating prescription drug expenditure in the United States
– an indicator of pharmaceutical market dynamics in the absence of regulation

Pharmaceutical Spending Revisited¹



¹Data sources: Germany (drug expenditure by GKV), WHO, Schwabe and Patzsch 1993 – 2002; USA (retail spending on prescription drugs), American Institutes for Research (AIR) analysis of Scott-Levin data

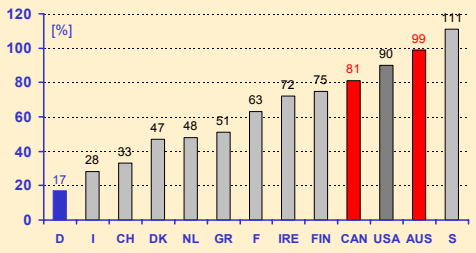
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BACKGROUND

German component management and "fourth hurdle" regulation:
impact on pharmaceutical spending dynamics

Total Pharmaceutical Spending
(real per-capita growth 1990-2001)¹

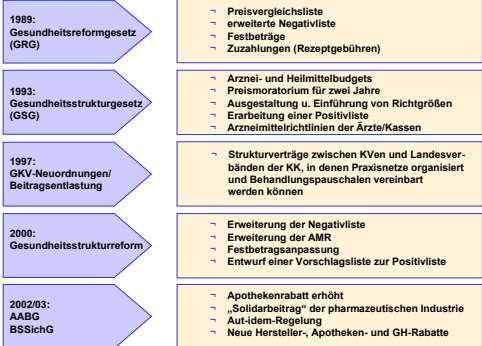


¹Schlender (2004), data source: OECD Health Data 2003; Australia and Switzerland: 1990-2000; Germany: 1990-2001



GERMAN HEALTH CARE REFORMS

Regulation of German pharmaceutical market before enactment of the GMG – some highlights

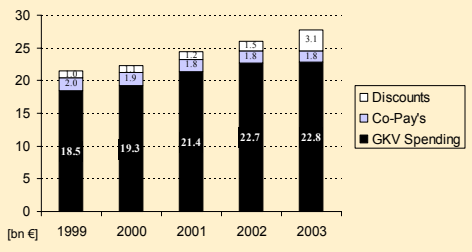


GERMAN HEALTH CARE REFORMS

German pharmaceutical spending:

SHI (GKV) spending, copayments (by patients), mandated discounts to GKV

Market Evolution 1999-2003¹



¹U. Schwabe, D. Paffrath: Arzneivorteilhaftigkeitsgesetz 2004, p. 139



POLITICAL DEBATE IN GERMANY

Focus on pharmaceutical spending (Germany, summer 2003)



An Inappropriate Response by Industry



- ↳ „Ein staatliches Zentralinstitut führt zwangsläufig zur Einheitsversorgung.“¹
- ↳ „Die Attraktivität ausländischer Pharmastandorte würde durch ein solches Gesetzesvorhaben [gemeint ist die „vierte Hürde“] weiter erhöht.“¹
- ↳ „Viele VFA-Mitgliedsunternehmen ... werden sich gezwungen sehen, Investitionen am Standort Deutschland einzufrieren und zukunftsfähige Arbeitsplätze abzubauen.“¹
- ↳ „Es ist eine absolute Illusion, daß zu irgendeinem Zeitpunkt ein Arzneimittel ... eindeutig ... bewertet werden kann.“²



- ↳ „Leben ist Vielfalt – stoppt die Einfall.“³
- ↳ „Unter dem Deckmäntelchen der Pharmakoökonomie geht es weiterhin ... Immer nur darum, an genau den falschen Stellen, Gelder einzusparen.“⁴

VFA: „Positionspapier: Staatliches Institut als Arzneimittel-Innovationshürde“, 2. Februar 2003; Quelle: Ärzte-Zeitung vom 23.05.2003; BPI: Kampagne gegen die Positivliste (2001); ¹ Rothermund (Vorstandmitglied des BPI) am 17.06.2002 in Leverkusen; ebenso auch bezogen auf Cineclidin (sic): „Was es nicht gibt: Pharmakoökonomie gewesen, hier einmal den gesamten volkswirtschaftlichen Nutzen eines solchen Arzneimittels zu untersuchen.“

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Pharmaceutical Politics in Germany 2005



GERMAN HEALTH CARE REFORM ACT 2004

In clinical medicine, the sheer number of changes in pharmaceutical regulation implemented with the GMG would easily qualify as “polypharmacy”



New Regulations of GMG, effective 2004

- ↳ **Modified cost-sharing policies**
 - ↳ Including change of social hardship clauses and exempts
- ↳ **Extended reference pricing policies (levels 2 and 3)**
- ↳ **Temporary increase of mandated manufacturers' discount**
 - ↳ 16% in 2004 (6% before and after 2004), beneficiary = statutory health insurance
- ↳ **Formal evaluation of incremental (clinical) “benefits” (not: cost-effectiveness)**
 - ↳ Primarily of prescription drugs by new institute (IQWiG) “A/B” vs. “C/D”
- ↳ **Various modifications of the (highly regulated) distribution system**
- ↳ **Entirely new system of pharmacy mark-ups**
 - ↳ As of 2004: €8.10 + 3% of wholesale (= pharmacy acquisition) price
- ↳ **Exclusion from reimbursement of OTC products**
 - ↳ Numerous exceptions (e.g., children < 18 years)
- ↳ **Deregulation of ex-pharmacy pricing for OTC products**

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GERMAN HEALTH CARE REFORM ACT 2004

Gesundheitspolitik in Deutschland: „Nutzenbewertungen“

– Une Simplifaction Terrible?



Neuregelungen GMG 2004

- ↳ **Neue Arzneimittel!**
 - ↳ **Konsens vom 22. Juli 2003:**
„Eine Kosten-Nutzen-Bewertung findet nicht statt.“
 - ↳ **Gesetz vom 8. September 2003:**
 - ↳ **Nutzenbewertungen:** „Das Institut bestimmt einheitliche Methoden für die Erarbeitung der Bewertungen.“ (SGB V, §35b)
 - ↳ „Nach gegenwärtigem Erkenntnisstand sinnvoll“:
 - ↳ **A:** Verbesserte Wirkung / neues Wirkprinzip
 - ↳ **B:** Verbesserte Wirkung / bekanntes Wirkprinzip
 - ↳ **C:** Ohne verbesserte Wirkung -> **Festbetragsgruppe Stufe 2**
 - ↳ A/B: setzen „einen für die Therapie bedeutsamen höheren Nutzen für die überwiegende Zahl der Patienten“ gegenüber dem bisherigen Therapiestandard voraus

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GERMAN HEALTH CARE REFORM ACT 2004

Gesundheitspolitik in Deutschland
„Nutzenbewertungen“

Klassifizierung nach Fricke und Klaus¹

Neue Arzneimittel:

- „Ausreichende therapeutische Erfahrungen auf breiter Basis ... fehlen ... Die Bewertung der Arzneimittel kann daher prinzipiell nur vorläufig sein.“¹
- „Die Bewertung orientiert sich an der jeweils aktuellen Marktsituation. Sie erfolgt ... nach allgemeinen pharmakologischen und therapeutischen Erfahrungskriterien. **Letztlich stellt sie jedoch die – wenn auch aufgrund der jeweils aktuellen Sachlage gewonnene – persönliche Meinung der Autoren dar.**“¹
 - A: Innovative Struktur oder neuartiges Wirkprinzip mit therapeutischer Relevanz
 - B: Verbesserung pharmakodynamischer oder pharmakokinetischer Eigenschaften bereits bekannter Wirkprinzipien
 - C: Analogpräparat mit kleinen oder nur marginalen Unterschieden zu bereits eingeführten Präparaten
 - D: Nicht ausreichend gesichertes Wirkprinzip oder unklarer therapeutischer Stellenwert

¹Fricke, Klaus (2003): „Neue Arzneimittel“, Bd.13, S.14f.

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GERMAN HEALTH CARE REFORM ACT 2004

Gemeinsamer Bundesausschuß (GemBA):
Entscheidungsgrundlagen der Festbetragsgruppenbildung

GemBA-Kriterien vom 15. Februar 2005

- Ausgenommen von der Gruppenbildung sind Arzneimittel mit patentgeschützten Wirkstoffen, die eine **therapeutische Verbesserung**, auch wegen geringerer Nebenwirkungen, bedeuten - insbesondere:
 - überlegene Wirksamkeit
 - besondere Leistungsmerkmale (zum Beispiel Applikationsort, Applikationsweg, bedeutsame andere Galenik)
 - geringere Nebenwirkungen
- Geringere Nebenwirkung** kann im Vergleich mit anderen Wirkstoffen der Vergleichsgruppe der Wegfall oder die erhebliche Verringerung des Häufigkeitsgrades einer therapierelevanten (Fassung vom 15.06.2004: „schwerwiegenden“) Nebenwirkung sein.
- Unterlagen für den **Nachweis** einer therapeutischen Verbesserung:
 - Direkte Vergleichsstudie guter Qualität anhand klinisch relevanter Endpunkte – soll an Populationen oder unter Bedingungen durchgeführt sein, die für die übliche Behandlungssituation repräsentativ und relevant sind...

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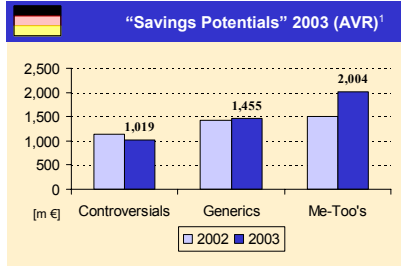
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- Market situation after enactment of the GMG
- Overuse, misuse, and underutilization



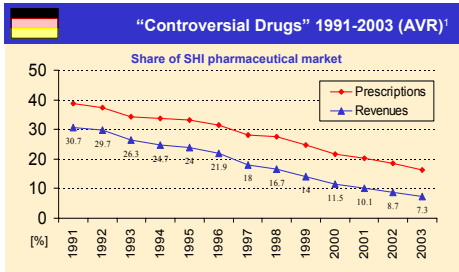
QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Situation **"before"** enactment of the GKV Modernization Act (GMG):
 Pharmaceutical component management ("drug budget silo mentality"),
 Above-average growth of pharmaceutical spending since 1995, and "savings potential"
 (overuse and misuse, according to Schwabe und Paffrath)

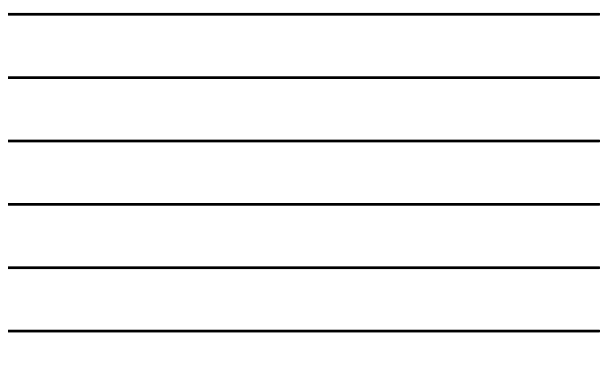


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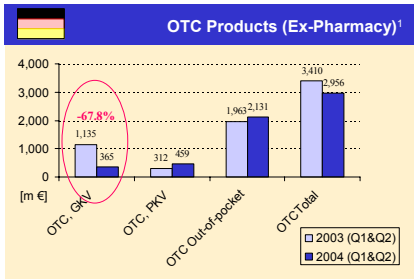


¹Data source: U. Schwabe, D. Paffrath: Arzneiverordnungsreport 2004, p. 31
 Revenues 2003: 1.8 bn €; calculated savings potential: 1.9 bn €;
 SHI, Statutory Health Insurance (Gesetzliche Krankenversicherung, GKV)



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Situation **"after"** enactment of the GKV Modernization Act (GMG):
 Exclusion from reimbursement of (most) OTC products,
 resulting market shifts

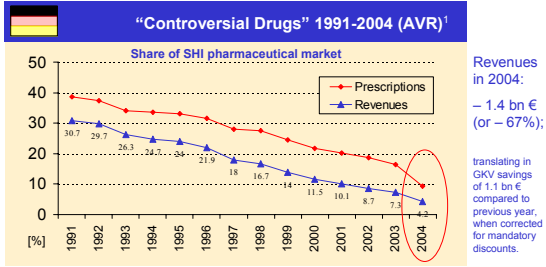


¹Data source: IMS Health, Frankfurt a.M. 09/2004.
 GKV, Gesetzliche Krankenversicherung (statutory health insurance, SHI);
 PKV, Private Krankenversicherung (private health insurance)



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Situation **"after"** enactment of the GKV Modernization Act (GMG):
Many OTC products excluded from reimbursement
fall into the category of "controversial" products



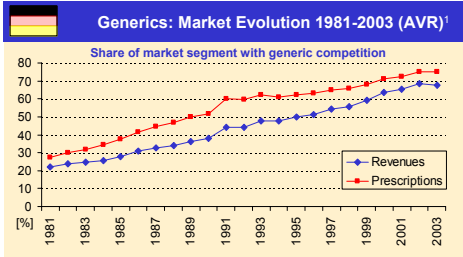
Revenues in 2004:
 – 1.4 bn €
 (or – 67%);
 translating in GKV savings of 1.1 bn € compared to previous year, when corrected for mandatory discounts.

¹Data source: U. Schwabe, D. Paffrath: Arzneiverordnungsreport 2005



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

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Pharmaceutical component management ("drug budget silo mentality"),
Above-average growth of pharmaceutical spending since 1995, and "savings potential" (overuse and misuse, according to Schwabe und Paffrath)¹

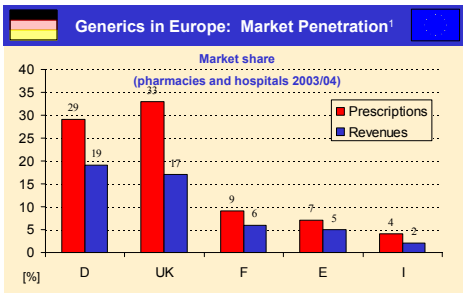


¹Data source: U. Schwabe, D. Paffrath: Arzneiverordnungsreport 2004, pp. 14, 15, 32; generic revenues 2003: ca. 7.5 bn € (market segment with generic competition: 9.9 bn €); calculated additional (theoretical) savings potential: 1.45 bn €



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

High generic market penetration in Germany:
Comparison of major European pharmaceutical markets¹



¹Source: IMS Health, MIDAS MAT 03/2004



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

“Germany is characterized by a positive attitude to generics”¹

Country	Average market penetration (share) after 4 years	Average difference between brand & generic price after 4 years
UK	55	80
NL	35	50
D	45	30
F	5-15	30
I	5-15	25
E	5-15	25

¹Source: IMS Health, May 04, 2004

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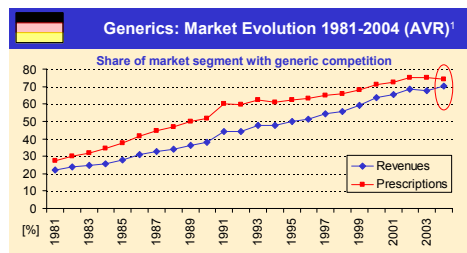
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QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Situation “after” enactment of the GKV Modernization Act (GMG):

Increasing share of generics by revenues is due to profoundly changed regulation of pharmacy mark-ups



¹Data source: U. Schwabe, D. Puffrath: Arzneiverordnungsreport 2005, pp. 15ff.; generic revenues (2004), 7.4 bn € (market segment with generic competition: 10.6 bn €); calculated remaining (theoretical) savings potential: 1.06 bn €

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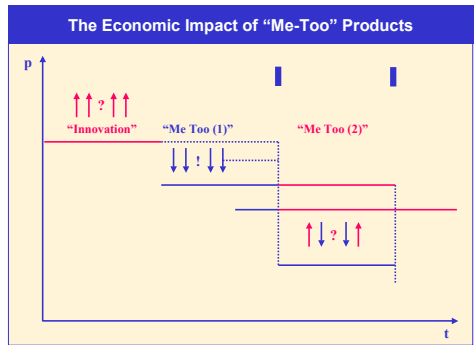
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Product life cycle phases heavily influence the economic impact of “me-too” products



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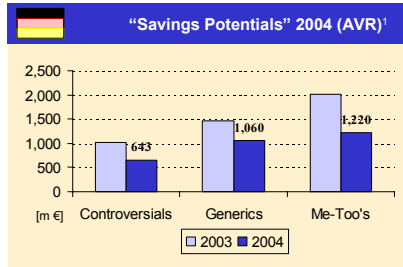
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QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Situation "after" enactment of the GKV Modernization Act (GMG):
Estimates of remaining (theoretical) "savings potentials"
(overuse and misuse, according to Schwabe und Paffrath¹)



¹J. Schwabe, D. Paffrath: Arzneiverordnungsreport 2005;
note that the increased manufacturers' discount to the GKV was introduced to anticipate savings expected in the "me-too" market segment due to the introduction of reference pricing level 2 - however, the implementation of reference prices has turned out to be a more time consuming process than anticipated, resulting in lower savings in 2005 than expected



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

An increasing number of studies are suggesting
underutilization of effective pharmaceuticals in Germany

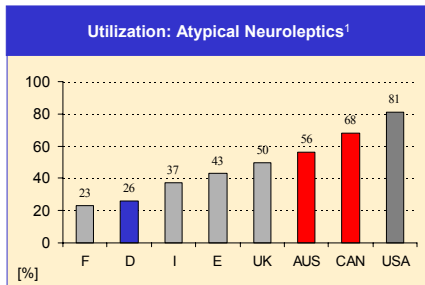
**Underutilization
exceeding overuse and misuse?**

- ↳ **Sachverständigenrat (SVR) 2001:**
 - ↳ Underuse amounting to 8.6 bn DM (~4.4 bn €)
- ↳ **Kassenärztliche Bundesvereinigung (KBV) 2005:**
 - ↳ Underuse in seven indications investigated amounting to 2.7 bn €
- ↳ **Trade-offs between first-order and second-order efficiency?**
 - ↳ (Over-)emphasis on static efficiency ?



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An example of underutilization of innovative drugs in Germany:
atypical neuroleptics as a percentage of total antipsychotic prescriptions



¹Source: VFA-Gutachten by Fricke & Pisk, October 12, 2004, based on IMS data, Q1, 2004



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Health or Medical Technology Assessments (HTAs / MTAs)

Evaluation of "clinical benefits" (only) by IQWiG in Germany: There are Better Alternatives¹

- Evaluating the **cost-effectiveness** of medical interventions represents a powerful tool to inform rational decision-making.
- Evidence of **clinical effectiveness** may serve as a pragmatic starting point, as there is no cost-effectiveness without it.
- There is no rationale to use different **criteria** for new vs. established products (nor for drugs vs. non-pharmaceutical interventions).
- Interventions may be **prioritized for appraisal** according to their relevance, i.e. their **opportunity cost** (or "budgetary impact").
- Assuming a (hypothetical) "**relevance threshold**" of 20m € annual revenues, this would result in ~200 products to be evaluated².
- Appraisal processes should be conducted **independently** from stakeholders (e.g., third-party payers, industry, etc.).

¹M. Schlender (2003): 'a perfectly feasible number: a total of 200 products would result in 67 evaluations (assuming groups of three products can be formed) which in turn would result in 22 evaluations p.a. (assuming an update will be made every three years on average).

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QUALITY & EFFICIENCY OF PHARMACOTHERAPY

Health or Medical Technology Assessments (HTAs / MTAs):
There are better alternatives

Might NICE Serve as a Role Model?

- **Predictable, transparent process**
 - Participatory nature of process
- **Transparency highly acclaimed**
 - **But:** commercial-in-confidence (CIC) data?
 - **But:** vague (...) meeting minutes?
 - **But:** conflicts of interest of Assessment Group members?
- **Methods highly standardized**
 - **But:** at the expense of (required) flexibility?
 - **But:** at the expense of losing (potentially huge amounts of) information?
 - **But:** may need quality assurance of assessments commissioned?
 - **But:** hindering further development of H.E. methods?
- **But: Deep divide between economic and clinical functions**
 - Including normative assumptions?

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IV

GERMAN FEDERAL ELECTIONS 2005

- The New Political Landscape
- Some Preliminary Perspectives

IV

THE BIG PICTURE IN FALL 2005

Situation Germany Fall 2005

Market Development 2004 / 2005

- ↪ **GMG architects ignored structural dynamics of pharmaceutical market**
 - ↪ Data (time series) for 2004 difficult to interpret
 - ↪ Plethora of GMG measures ("polypharmacy")
 - ↪ SHI market 2004: 21.7 bn € (2003: 24.1 bn €), minus 10.2%
 - ↪ Prescription only segment -4.7%
 - ↪ Generic market penetration constant at ~75%
 - ↪ Controversial products -48% (minus 917m €)
- ↪ **Massive growth of pharmaceutical spending in 2005 (Q1-Q3, +~20%)**
 - ↪ First appraisals by IQWiG now published
 - ↪ Manufacturers' discount reduced again (to 6%)
 - ↪ But implementation of reference prices (level 2) slower than expected
 - ↪ "Structural component" growth exceeding 10%



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The new political landscape

Situation Germany Fall 2005

- ↪ **Political agenda before September 18, 2005**
 - ↪ CDU: "Kopfpauschale" (idea: fixed insurance premiums per capita)
 - ↪ SPD: "Bürgerversicherung" (idea: SHI coverage mandatory for whole population)
 - ↪ CDU/CSU: a murky compromise between the above
 - ↪ FDP: full liberalization / deregulation of health insurance (idea: a basic package mandatory for all; subsidies to the poor)
 - ↪ CDU: vision of a flat income tax (P. Kirchhof)
 - ↪ Fiscal incompatibility of social subsidies and tax schemes proposed (CDU/CSU, FDP)
- ↪ **After the federal election: a "Grand Coalition" (CDU/CSU and SPD) most likely**
 - ↪ After four weeks, agreement reached on key personnel only: chancellor (Angela Merkel) and minister positions (U. Schmidt to remain as health minister, H. Seehofer to join the administration again)
 - ↪ Future directions still unclear; in the past, key players have placed emphasis on regulation and cost-containment



QUALITY & EFFICIENCY OF PHARMACOTHERAPY

What to expect?

Situation Germany Fall 2005

- ↪ End of 2004: Pharmaceutical underutilization now most likely exceeding overuse
- ↪ Pharmaceutical market growth in 2005 (Q1-Q3: +~20%) far beyond expectations
- ↪ Potential for future savings ("*headroom for innovation*") largely exhausted
 - ↪ Controversial products, generic substitution, me too's
- ↪ IQWiG currently doing effectiveness reviews only
 - ↪ Focus on two categories of benefit (A,B versus C, D)
- ↪ Political parties (conservatives, social democrats) neutralizing each other
 - ↪ Major reform most unlikely ("familiar faces": U. Schmidt, H. Seehofer, K. Lauterbach)
 - ↪ Muddling-through likely to continue; implication: expect haphazard interventions ...
- ↪ **Further pharmaceutical cost-containment measures imminent**
 - ↪ With few exceptions, component management likely to prevail
 - ↪ Implementation of reference pricing level 3 (therapeutically equivalent products) likely
 - ↪ Moving from effectiveness reviews to cost-effectiveness evaluation (?)