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Abstract: Introduction: Since April 2007, health insurance funds in Germany are entitled to negotiate drug discount contracts (DDCs) with pharmaceutical manufacturers on particular drugs. DDCs commit pharmacists to dispense the drug made by this manufacturer. The aim of this study was to examine, how DDCs are implemented in pharmacies routines, and what implications DDCs have for everyday drug supply. Methods: A standardized questionnaire on DDCs and their impact on drug supply was developed according to previous literature, piloted and distributed to pharmacies in Baden-Württemberg. Results: 804 pharmacists and pharmaceutical assistants participated in the study. The implementation of DDCs implies significant extra work for pharmacists, particularly additional need for counselling and education (99.1%), additional logistical requirements and more complex data processing needs. Patients are reported to get confused (97%), angry (96.9%) about intransparent drug substitutions, medication errors occur (60.1%). Conclusion: DDCs besides implications for prescribers and patients also have substantial impact on pharmacists and pharmacies. Adverse effects on drug supply and medication safety are possible or likely.

Response to Reviewers: please find enclosed attache file "list of changes"

Impact of drug discount contracts on pharmacies and on patients' drug supply

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Impact of drug discount contracts on pharmacies and on patients' drug supply

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4 **Introduction:** Since April 2007, health insurance funds in Germany are entitled to negotiate
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6 drug discount contracts (DDCs) with pharmaceutical manufacturers on particular drugs.
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8 DDCs commit pharmacists to dispense the drug made by this manufacturer. The aim of this
9
10 study was to examine, how DDCs are implemented in pharmacies routines, and what
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24 needs. Patients are reported to get confused (97%), angry (96.9%) about intransparent drug
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26 substitutions, medication errors occur (60.1%). **Conclusion:** DDCs besides implications for
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28 prescribers and patients also have substantial impact on pharmacists and pharmacies. Adverse
29
30 effects on drug supply and medication safety are possible or likely.
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39 Keywords: drug discount contracts, pharmacists, drug switching, substitution, drug safety

40 List of abbreviations: DDC= drug discount contracts
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45 **Background**

46
47 In Germany, a recently (April 2007) reformed federal Health Insurance Act (*Sozialgesetzbuch*
48
49 *5, SGB V*) entitles health insurance funds to make contracts with pharmaceutical
50
51 manufacturers pertaining that members of the fund get the drug of the contract partner if
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53 prescribed an active ingredient regulated by the contract. If a patient holds a prescription of a
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55 brand name drug of a different manufacturer but the contract partner, pharmacists are liable
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57 not to hand out the prescribed but the contract-drug within certain substitution rules listed
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4 Doctors may bypass the regulation for medical reasons by prescribing a brand name drug and
5 ticking the 'aut-idem-tickbox' in the prescription form assuring that an individual patient gets
6 hold of a particular brand name drug but discharging the Health Insurance Fund in part from
7 their obligation to pay for the drug.
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10 The aim of the legal regulation is to reduce expenses by cheaper drug supply.
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14 Substitution rules include

- 15 - identical active ingredient
- 16 - identical dosage
- 17 - identical package size
- 18 - same indication

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20 and the same or exchangeable galenics. The composition of additives (eg. alcohol, allergens,
21 etc.) and also splitting properties of tablets to be substituted may vary (Pruszydlo et al. 2008).
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24 Despite detailed substitution rules patients have to face frequent changes in drug design and
25 packaging.
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28 There is evidence that substitution of drugs may result in relevant patients' confusion and
29 medication errors (De Smet et al. 2007; Brekke et al. 2008; Sorensen et al. 2006) and that
30 consultations with prescribing physicians are necessary (Hibbeler 2007). But it has been
31 hardly explored what impact drug discount contracts have on the interaction of pharmacists
32 and patients and what implication drug discount contracts have for patients' information
33 needs.
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44 As of August 2009, most of 186 health insurance funds and nearly 139 manufacturers
45 participate in one or more of these discount contracts. To date, there are drug discount
46 contracts concerning 29.206 drugs (Maag 2009) of roughly 56.660 (Pharma-Daten 2008)
47 licensed in Germany. In 2009, the rate of rebated drugs amounts to 75% (Maag 2009).
48 Logistics and management of substitution of such a huge amount of drugs is growing more
49 complex and actually requires more than 18 million data sets to be controlled for in any
50 prescription (Keller 2008). Also, logistics for procurement of drugs has become more
51 complex and more prone to errors. In times when the first contracts started, there were often
52 difficulties in the delivery by the pharmaceutical manufacturers. Storage capacity of
53 pharmacies had to be extended (Hibbeler 2007).
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4 Patients might be confused or feel frightened if they receive drugs with a modified package,
5 similar drug names and tablets in a different shape, color or divisibility than the used one
6 (Aronson 2004). Medication errors have been reported, the need for additional diagnostic and
7 therapeutic procedures has been suspected and substantial individual health impact cannot be
8 excluded. (Krämer et al. 2008, Meyer 2009, Otterbach 2008).
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14 Additional information needs and guidance provoke increasing service times in pharmacies
15 with impact on patient/customer satisfaction. Also pharmacies' customers get annoyed about
16 long waiting times at the pharmacies, because the customers need additional guidance or their
17 drug isn't available. Reliance between customer and pharmacist and drug adherence might
18 suffer.
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25 So far, data on the impact of drug discount contracts to pharmacists, physician and patients
26 are sparse. The aim of this study is to investigate how DDCs are implemented and what
27 impact they have. To have an overview over their effects, affected groups, i.e. patients,
28 doctors and pharmacists, were interviewed by self administered questionnaire about their
29 experience with these contracts. Results of 2 studies have been submitted for publication.
30 Here, data about the impact of drug discount contracts on pharmacies and on patients' drug
31 supply are reported.
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38 **Methods**

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40 For an overview of previous research on drug discount contracts a literature search in
41 MEDLINE, EMBASE and COCHRANE was performed using keywords "drug discount
42 contracts" or "compliance" or "tablet splitting," "drug switching" or "generic substitution" or
43 "aut idem" or "adherence". In addition, a handsearch in german language journals such as
44 "Zeitschrift für Allgemeinmedizin", "Deutsche Ärztezeitung" or the "Pharmazeutische
45 Zeitung" was done.
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53 Based on this literature review and in collaboration with pharmacists, a questionnaire for
54 pharmacies was developed and piloted in an iterative process. The survey instrument contains
55 sociodemographic data like age, gender, profession and years of professional practice and
56 data about the environment of the pharmacy. Participants were asked what impact drug
57 discount contracts have on their daily work, about their difficulties with respect to staff and
58 storage of the additional drugs, about information need, the behaviour of the patient`s
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4 handling of the progress of substitution. Questions were answered by Likert-type answering
5 scales ("true", "likely to be true," "tend not to be true" and "does not apply to") (Jamieson
6 2004).
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10 The questionnaire was distributed as supplement in the member journal of
11 "Landesapothekenkammer Baden-Württemberg"(Regional Chamber of Pharmacists) named
12 "COSMAS" and was send out by the chamber to approx. 2750 pharmacies in B.-W. The
13 questionnaire was returned anonymously to the authors.
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19 The study was approved by the Universities internal review board (No. 190/08).
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23 **Data processing and Statistics**

24 Data were entered in a SAS database randomly controlled for correct input and evaluated by
25 means of descriptive statistics. All variables were initially evaluated descriptively, analytical
26 statistics was performed if applicable.
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31 **Results**

32 The survey was conducted between September – December 2008. 804 questionnaires were
33 returned from pharmacists (82.3%), PTA (pharmacist`s assistant) (13.7%) and PKA
34 (pharmaceutical sales assistant) or other professions (4%) (PKA/other). 38% of respondents
35 are male.
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42 In table 1 basic characteristics of the sample are presented.
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45 Furtheron, responses are reported without reference to professional level, unless otherwise
46 noted.
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Table 1**Presentation of individual items**

A substantial majority of respondents (69%) report that they rarely get prescriptions that exclude substitution (“aut-idem-tickbox” ticked), and 30.9% report they get some such prescriptions.

According to pharmacists`questionnaire, they usually (82.5% on a Likert scale) receive prescriptions with the drug`s brand name on it. In contrast to other European countries, German pharmacists seldom receive prescriptions with the drug`s active ingredient noted (79.8% rejection on a Likert scale) (Figure 1).

Figure 1

A vast majority of respondents (98.3%) often have to switch drugs due to DDCs, and almost half of them (45.3%) admit that they occasionally do not have appropriate drugs for substitution in stock. 45.1 % report shortages of supply of appropriate drugs, and some 31% have encountered delivery problems of these drugs. Less than one fourth did not have substantial (21.6%) or did not have any (1.9%) supply problems with discount-drugs.

One of the critiques against drug substitution is that splitting properties of tablets might differ substantially. 65.7 % (48.4 + 17.3) of pharmacists or their employees don`t know exactly about the splitting properties of individual drugs handed over to patients (Figure 2).

Figure 2

Almost all respondents (96.9%) report that customers react angry about getting an unknown drug. 97% of interviewees note that in their opinion the patients feel confused about handling of their drugs resulting from DDCs. Furthermore, 60.1% respondents specify that they know about medications errors of patients due to DDCs (Figure 3).

Figure 3

A vast majority (99.1%) report increased need for patients` counselling. 99.3% stated that the discount contracts have an important impact on the daily business. 93.8% indicate additional personnel expenses with respect to additional delivering servives of drugs to the patients. In

Germany if a specific drug is not on stock in the pharmacy they order it and will deliver the medication to patient's home, usually on the same day (Figure 4).

Figure 4

In table 2, we present the results concerning extra payments, customers behaviour with respect to swapping drugs and additional patients` waiting time due to DDC.

About 85% (24.5% and 59.9 % respectively) of respondents note that it happens more than 5 times a week, that patients ask for not substituting their previously known drug, and 70 % (27.9 % and 42.2 % respectively) say that at least 5 times a week customers not only ask for, but insist on receiving their known drug. Likewise customers have to accept additional waiting time due to increased counselling and occasionally even higher surcharges. Furthermore over 70% report that they got threats of repayments ("Retaxierung") by the health insurances up to 10 times per month (Table 2).

Table 2

Discussion

By reforming the Health Insurance Act in 2007 and implementing drug discount contracts, new instruments have been effective in the regulation of drug supply installed with the aim to reduce cost for the Health Insurance Funds.

Pharmacists now are overwhelmed by the sheer amount of 28.000 DCCs they have to control for each individual patient's medication.

The administration of drug discount contracts denotes a significant additional burden for pharmacies. This arises primarily due to the significant demand for explanation by the patient, manpower requirements, the challenging logistics and the technical processing of data. Additional personnel expenses by an additional service (delivery service) and a high increase of advice required by the customers have an important influence on the daily business. Also, half of the pharmacists do not know exactly if the substitution tablet is as well and exact divisible as the substituted one was. They must additionally look up in the Formulary. Pharmacists do have an increased need for patient-information and consultation due to the discount contracts.

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4 But not only pharmacists bear an additional burden by the DDCs. Patients showed the same
5 inconvenience. Medication errors do occur (Rucker et al.; Mahler et al). It is evident that
6 patients feel confused and angry because of the substitution (Rucker 2007; Wahl 2008). This
7 also reflects in patients` behavior towards pharmacists, because patients very often insist on
8 or ask for their well-known medicine. Patients have more waiting time because of more
9 additional advice or by delivery problems of the pharmaceutical companies (Haffke 2008).
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16 Physicians might specify not to change the prescribed drug on the prescription form to make
17 sure that the patient continues to receive his usual medication. According to surveys by the
18 „Kassenarztlichen Vereinigung Nordrhein“ (Association of Statutory Health Insurance
19 Physicians, Northrhine) majority of physicians never or only in individual cases are ticking
20 the box “aut idem” (Neye 2008). This may be, because physicians are held liable for
21 uneconomic prescription, on the part of the health insurance companies (Manthey 2008).
22 Same applies for pharmacists. If they do not deliver the particular rebate drugs of the health
23 insurance companies` contractors, they might be held liable in a procedure called
24 “Retaxierung” for additional costs of non-contractors` drugs by the health insurance funds
25 (Ehlers et al. 2001).
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35 Now, with DCCs in effect, health insurance funds directly interfere with historically evolved
36 structures in the health care system. DCCs impose a fundamental reorganization of
37 Germany`s drug supply by administrative means. Pharmacies` and pharmacists` self-concept
38 and relationship to customers changes fundamentally.
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43 In the long run, pharmacies in Germany might have to give up their traditional role as an
44 independent player and stakeholder in the health care system and turn more into a
45 “dispensary-style” pharmacy to hand out a drug previously negotiated between health care
46 funds and drug manufacturers.
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53 **Limitations of the study**

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55 Fundamental limitation of this study is the restriction to self reported appreciation of the
56 impact of DDCs of pharmacists` poise/attitude to medication supply and to self reported
57 behaviour. No direct observations of pharmacists` were made, reliability of pharmacists`
58 statements remains unknown. In this study, patients` attitudes have only been reported by best
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guess of pharmacists, no direct patient-generated data was part of this manuscript. Data of physicians' and patients' self reported attitudes are reported elsewhere.

Due to a lack of basic data, this study could not be designed to evaluate effect size of DDCs' impact on patients' drug supply, medication adherence, potential adverse events and patients' well being.

Conclusion

The DDCs denote a significant intervention in drug therapy. Pharmacists report on medication errors on the part of patients because of the discount contracts. Medication safety seems to be at risk. Further studies e.g. analysis of secondary data and for direct observations are necessary to evaluate the effect of these contracts agreements. The aim of the discount contracts should not focus on monetary aspects alone. One of the major ethical aims of modern medicine is respect for patients' autonomy and it might be affected by DDCs.

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Conflict of interest

The authors declare that they have no conflict of interest.

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Figure

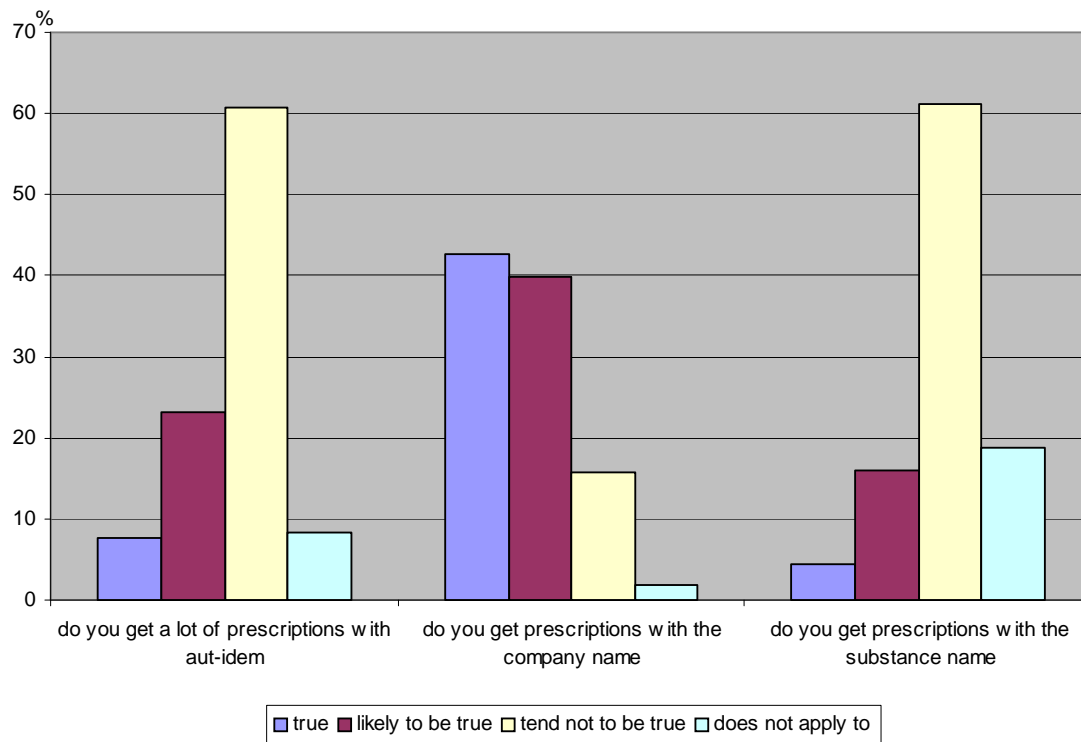


Figure 1: Evaluation of the prescriptions. (Results of a four step Likert scale)

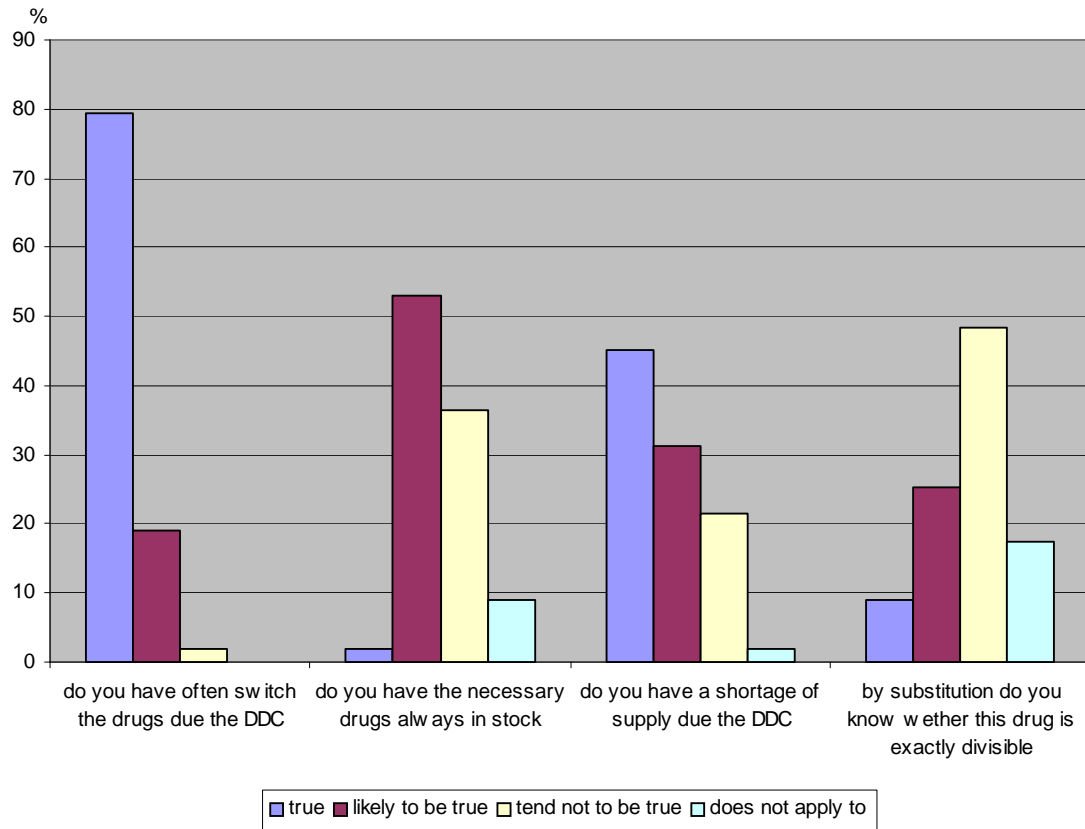


Figure 2 : Evaluation of the discount agreements with respect to storage, shortages of supply, the frequency of switching drugs and the knowledge of splitting of the tablets. (Results of a four step Likert scale – DDC= drug discount contracts)

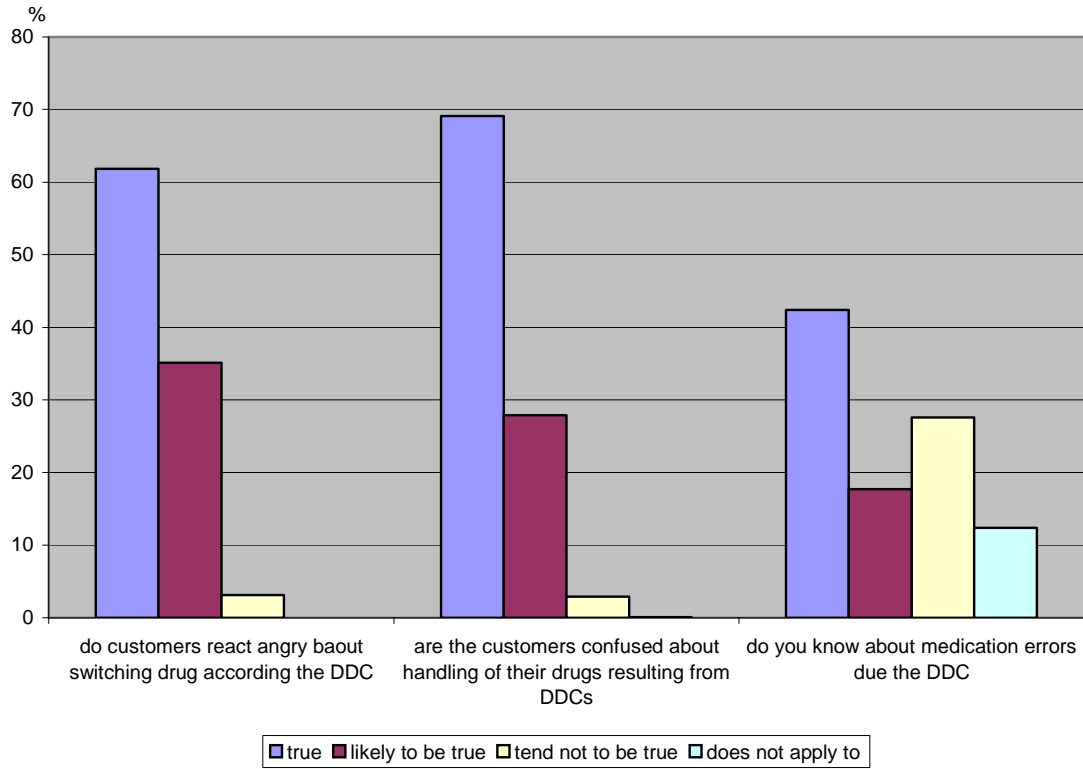


Figure 3: Evaluation of the drug discount contracts with respect to customers behaviour, medications intake and medication errors. . (Results of a four step Likert scale - DDC= drug discount contracts)

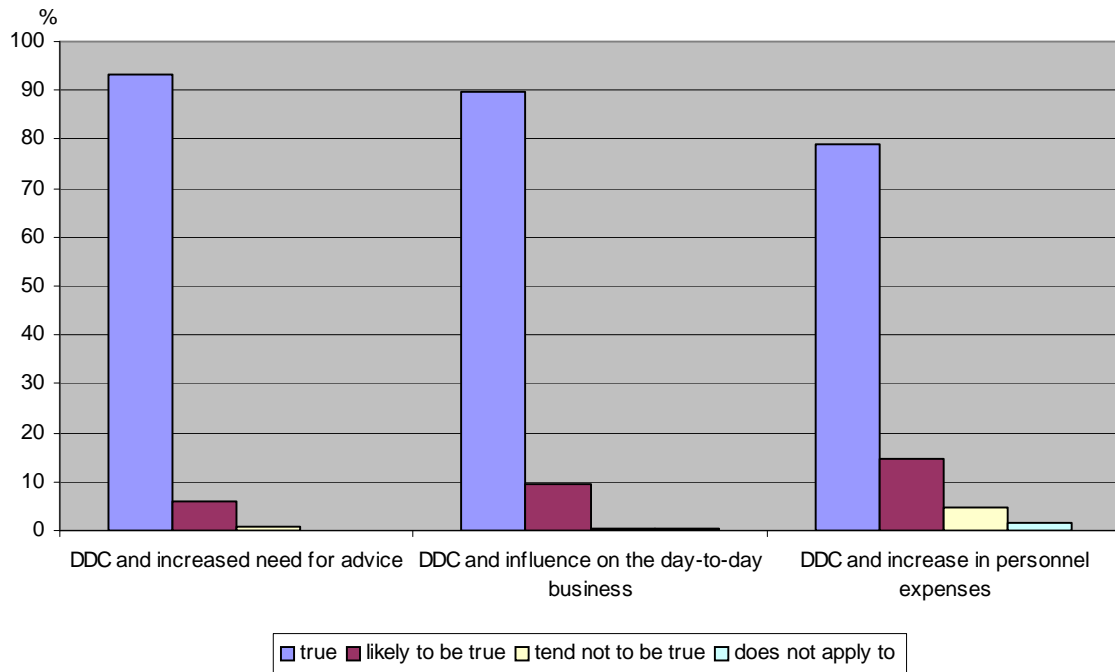


Figure 4: Evaluation of the discount agreements with respect to advice, additional personnel and the influence on the day-to-day business. (Results of a four step Likert scale - DDC= drug discount contracts)

Table 1: Age, years of profession by pharmacists, PTA, PKA/ other professions and pharmacy environment

			n	minimum	median	maximum	mean	SD
Age (years)	Pharmacists	male	289	26	53	86	51.9	10.4
	Pharmacists	female	337	25	47	83	47	10.5
	PTA	male	-	-	-	-	-	-
	PTA	female	105	17	37	60	36.8	11.1
	PKA/other	male	-	-	-	-	-	-
	PKA/other	female	31	19	45	64	43.5	12.8
years of profession			< 2 years	2-5 years	5-20 years	> 20 years		
Pharmacists			1.1%	5.7%	34.9%	58.3%		
PTA			9.4%	12.2%	45.8%	32.7%		
PKA/other female			6.5%	6.5%	32.3%	54.8%		
Pharmacy environment			rural	suburb/provincial	rather metropolitan			
			36.8%	48.9%	14.4%			

Table 2: Additional communication between pharmacies and customers. Financial performance and additional waiting time for customers to switch medications based on the drug discount contracts

	never	quite rare	often
Does it happens that customers have to pay more extra payment than before implementation of DDCs?	10.4%	80%	9.6%

	never	<5 times	5-10 times	> 10 times
During the last week, how often have customers asked for their well-known drug?	0.5%	15.1%	24.5%	59.9%
During the last week, how often did customers insist on their well-known drug?	0.4%	29.6%	27.9%	42.2%
During the last week, how often did customers suffer delay of delivery, because the discounted drug was out of stock?	0.6%	16.4%	23.9%	59.1%

	yes	no
Did your pharmacy get a threat of “Retaxierung”, which means financial loss by health insurance companys	70.1%	29.9%

	<5 times	5-10times	> 10 times
If yes. how many on average per month?	10.4%	80%	9.6%

List of changes

1. If a patient holds a prescription of a brand name drug of a different manufacturer but the contract partner, **pharmacists....**
2. Based on this literature review and in collaboration with pharmacists, a questionnaire for pharmacies was developed and piloted in **an** iterative process.
3. 93.8% indicate additional personnel expenses with respect to additional delivering services of **drugs** to the patients.
4. In Germany if a specific drug is not on stock in the pharmacy they order it and will deliver the medication to patient's home, usually on the same day (Figure 4).
~~Germany, traditionally, there is a service of lots of pharmacies. If a specific drug is not available, an employee will deliver medication to the patient's home, usually on the same day (Figure 4).~~
5. Additional personnel expenses by an additional service (delivery service) and a high **increase of advice required by the customers** have an important influence on the daily business.
6. This also reflects in patients` behavior towards pharmacists, because patients very often insist on or ask for their well-known medicine.
~~This also reflectes patient in behavior towards pharmacists , because patients very often insist or ak for their well known medicine”.~~
7. Patients ~~(do)~~ have more waiting time because of more additional advice or by delivery problems of the pharmaceutical companies (Haffke 2008).
8. In the long run, pharmacies in Germany might have to give up their traditional role as an independent players **s** and stakeholders **s** in the health care system