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## Sustainability of pharmaceutical expenditures in the German social health care system

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# **Sustainability of pharmaceutical expenditures in the German social health care system**

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# Abstract

## Background

Pharmaceutical expenditure grow strongly in most health care systems. Especially high prices of new drugs are perceived to be driver of growth which might threaten the sustainability of financing drugs.

## Objective

The study aims to analyse a) whether German health policies can achieve sustainable growth of pharmaceutical expenditure, and b) which therapeutic groups fasten and slow pharmaceutical growth based on price and/or volume effects.

## Methods

Annual growth rates of pharmaceutical expenditure in the German social health insurance (SHI) between 2006 and 2018 are compared with indicators reflecting the ability to pay. Annual growth rate in therapeutic subgroups are analysed with respects to volume and price developments.

## Results

Without policies to control pharmaceutical spending, annual growth rates are significantly higher than the growths of indicators of ability to pay. After accounting for the savings from health policy measures, net pharmaceutical expenditure does not grow significantly faster than ability to pay. Policies mainly targeting generic drugs achieve threefold savings compared with policies targeting at patent-protected drugs, although the latter account for more than halve of the expenditure. A limited number of therapeutic subgroups with new drugs grow significantly faster than average expenditure, but this growths is counterbalanced by subgroups which in the end of their innovation cycle and a huge proportion of generic drugs.

## Conclusion

The growths of net drug expenditure in the German SHI does not threaten the sustainability of financing health expenditure based on comprehensive policy measures and innovation cycle effects. Generics do contribute savings to a larger extent.

## Key points for decision makers:

- Germany efficiently uses a comprehensive set of health policies to control drug expenditure in the social health insurance with limited impact on reimbursement.
- Net drug expenditure grow on annual rates which correlate to ability to pay and thus do not threaten sustainability of health care financing.
- Natural progress of innovation cycles together with targeted policies on patent-protected as well as generic drugs counterbalance exaggerated growth in areas with a high degree of innovation.
- Policies targeted mainly on generic drugs yield threefold savings compared with policies targeting on patent-protected drugs. This imbalance should be considered in potential refinements of drug policies.

## 1. Introduction and objective

Pharmaceuticals largely contribute to the health of individuals and societies. In the US, 35% of the gain in life expectancy between 1990 and 2015 can be attributed to pharmaceuticals showing the value of drugs [1]. However, pharmaceutical expenditure and its growth are a matter of concern of health insurance companies and health politicians around the world. In OECD countries, pharmaceutical expenditure is steadily growing and accounts for about 20% of total health expenditure. Trends in pharmaceutical expenditure are influenced by price trends of existing and new drugs, changes in volume consumed and the mix of drugs used. Prices of existing drugs are stable or even declining due to regulation and generic competition. Usually, the availability of generics leads to significant price reductions [2]. The major drivers of expenditure are changes in drug quantities as well as new drugs. In several therapeutic classes new and more expensive drugs have entered the market during the last years. Prices of new specialty drugs or biologics are extremely high in some therapeutic areas like oncology or orphan diseases [3,4]. Delaying time to market was found to be a very powerful tool to reduce pharmaceutical expenditure. Worth noting, delaying time to access for innovative products was also identified as an effective leverage to increase savings but might not be a desirable policy for breakthrough products and limit access to medical progress [5]. Consumption of drugs has increased because of population ageing, growing prevalence of chronic diseases and changes in clinical practise. These trends raise the question on the efficiency of pharmaceutical spending and on their affordability [4,5].

Governments have adopted supply and demand side policies to control pharmaceutical expenditure [6]. Policy measures can target volume (e.g. coverage), price (by price cuts, distribution mark-ups, VAT, reference price policies) and therapeutic mix (by promotion of appropriate use) [3]. An OECD-study analysed such policies. User charges like co-payments do reduce utilization of pharmaceuticals, and reduce public expenditure by shifting costs to patients. But they reduce the use of essential as well as nonessential drugs. Without adequate exemptions, they affect vulnerable groups disproportionately. Physician-based measures appear to influence prescribing modestly, but it is essential that messages to prescribers are based on good evidence of efficacy and cost-effectiveness. Industry regulations like internal (therapeutic) reference pricing may result in cost savings. These regulation are, however, not always achieved by companies reducing or restraining prices, or by reductions in the overall volume of prescriptions, but by shifts in use and shifting costs to patients, with consequent adverse effects on the equity of access to medicines. Other price and profit controls remain almost completely lacking in evaluative evidence [3]. Another study found evidence that therapeutic reference pricing has intermediate policy effects, may reduce pharmaceutical prices and expenditures in the short term, and may lead to substitution effects towards lower-priced pharmaceuticals [7]. Ultimate policy effects on patient access, healthcare utilisation and R&D investments were found to be uncertain. No conclusions were drawn for external reference pricing and value based pricing [7]. This reviews show that many different policies are adopted with different effects on savings and access to medicines. Whether the measure can be used in a way to achieve financial sustainability was not explicitly analysed.

The major health policy goal is the provision of health care including pharmaceuticals under the constraints of access, efficiency, affordability and financial sustainability of the health care system. The OECD defines fiscal sustainability as the ability of a government to maintain public finances at a credible and serviceable position over the long term [8]. Financial sustainability is defined by the European Union as the ability to continue now and in the future current policies (with no changes regarding public services and taxation) without causing public debt to rise continuously as a share of GDP [9]. Sustainability of healthcare financing is a relevant basis for achieving the United Nations' sustainability development goal (SDG 3) to "ensure healthy lives and promote well-being for all at all ages" [10]. In the light of demographic changes, health care financing appears not to be sustainable in most countries due to inherent inefficiencies in healthcare delivery and payment [11]. Steps

towards sustainability can be achieved if health policy measures ensure that expenditure growth does not exceed the budget growth of the healthcare system. The objective of the study presented here is to analyse the health policies to regulate pharmaceutical expenditure in Germany with respect to sustainability.

The German health system is mainly financed within a statutory health insurance (SHI) system which covers approximately 90% of the German population in sickness funds. Pharmaceutical expenditures in the SHI accounts for 16% of overall SHI expenditure in 2018. Pharmaceutical prices and expenditure are publically debated based on annual reports like the Drug Prescription Report (AVR, Arzneiverordnungsreport [12]) or Innovation Report supported by the Techniker Sickness Fund [13]. Those reports focus on new drugs and their price regulation, because those drugs are seen as the main driver of expenditure growth. The reports come to the conclusion that many new drugs offer limited value and prices of new drugs increase strongly which might endanger the economic sustainability of the sickness funds [14]. This focus on new drugs might highlight one important growth driver, but disregards dynamics in the drug lifecycle. The introduction phase of new drugs is usually characterized by slow growth which results in limited expenditures during the first time after launch when prices are not yet regulated in Germany. A further dynamic is generic entry which lowers prices and might lead to decreasing expenditures [15]. In European countries, relative spending on usually high priced orphan drugs has increased between 2000 and 2017, but this has been largely compensated for within the current allocation of total pharmaceutical spending by flat expenditure for non-orphan drugs and increased volumes of lower-priced generics or biosimilars [16]. Thus, analysis of pharmaceutical expenditure should take a broader view in order to cope for the dynamics in the drug market.

Two aspects are analysed in this study. Firstly, the contribution of the policy measures undertaken to control drug expenditure are analysed over time. The overall growth of drug expenditure between 2006 and 2018 is compared with several indicators in order to assess whether overall growth is sustainable. These indicators are outlined in the methods section. Secondly, not only drugs, but also therapeutic classes go through lifecycles. The typical lifecycle of a drug after the first regulatory approval starts with an introduction phase with slow growth which is followed by a phase of strong growth and a phase of maturity. Growth is similar in quantities sold as well as sales achieved by the originator company, i.e. the company which developed the drug. After patent expiry, sales go down for the originator as generic companies enter the market (decline phase) [17]. When leaving the originator perspective, the lifecycle of the active ingredient of the drug is typically defined by a decrease in monetary sales. With regard to volumes sold, some active ingredients face further growth after patent expiry while other face a decline, i.e. especially when new originator drugs with added clinical benefit become available. This lifecycle is not unique to single drugs or active ingredients, but also to therapeutic groups, i.e. innovation cycles [15]. Depending on their position in the innovation cycles therapeutic groups can be drivers of pharmaceutical expenditure as well as have a moderating effect. It is analysed which therapeutic groups fasten and slow pharmaceutical growth based price and/or volume effects.

## 2. Methods

In the first part of the analysis, the annual growth rates of pharmaceutical expenditure in the SHI between 2006 and 2018 are analysed in relation to the growth rates of the overall health care expenditures in the SHI, the sum of basic salaries and the gross domestic product (GDP). Those indicators relate to the overall ability of the German economy and the health system to pay for drugs. The sum of basic salaries is the amount of income earned by SHI members from which they

have to pay their contributions to the SHI. These indicators reflect sustainability. If pharmaceutical expenditure does not grow on a higher rate than overall expenditure, drugs do not exceedingly conduce to the SHI contribution rates. If pharmaceutical expenditure does not grow faster than the sum of basic salaries, they do not increase contribution rates. If drug expenditure does not grow faster than GDP, its development is sustainable for the German economy. A further indicator is analysed to assess whether overall drug expenditure growth is adequate. It is analysed how the growth rates of pharmaceutical expenditure relate to the volume of drugs consumed measured by DDDs, the price index (inflation) and a combined price-volume-index covering the development of changes in drug consumption and overall prices. The price-volume-index reflects patients' needs for drugs which is influenced by demographics and epidemiology combined with the overall inflation which any individual or company faces. If the growth of drug expenditure is in line with the price-volume-index, growth rates of drug expenditure appear not to be exaggerated and thus adequate.

Three levels of drug expenditure are calculated based on the health care policies to regulate pharmaceutical SHI expenditure. Unfortunately, the effect of several policies cannot be quantified. First of all, prescription drugs are generally reimbursed in Germany, but the Social Security Code, Book V, allows exemption for life-style drugs and drugs against minor diseases like cough or sore throat as well as reimbursement restrictions or exclusions by the Federal Joint Committee (G-BA) which is the highest decision-making body of the joint self-government of physicians, hospitals and sickness funds in Germany. Secondly, physicians shall prescribe economically and regional physicians' associations take care of this, for instance through physician drug budgets or quotas for use of generic drugs. Thirdly, there is automatic substitution of drugs in pharmacies if cheaper drugs are available. While the effect of these measure on the drug expenditure cannot be quantified, other the impact of other measures can be quantified. Two measures target the list (gross) price of drugs, i.e. negotiation of reimbursement prices and fixed reference pricing. Reimbursement prices have been introduced in 2011 with the AMNOG legislation. New drugs can be priced without restrictions at launch and are reimbursed at this price for twelve months. Within the first year, a benefit assessment and a price negotiation take place. After one year, the list price must be lowered to the negotiated reimbursement price. Fixed reference prices are a form of internal (or therapeutic) reference pricing and target drug classes with generic competition. Fixed reference prices set an upper limit of the price to be paid for drugs by the SHI. Manufacturers are not obliged to decrease their list price to the fixed reference price, but most companies do so, because otherwise patients have to pay the price difference leading to significant decrease in packages sold. Based on the list prices and the savings due to reimbursement prices and fixed reference prices one can calculate list-price based expenditure and the "potential list-price" based drug expenditure. The latter reflects the expenditure in a hypothetical situation without fixed reference pricing and the AMNOG reimbursement prices. However, the SHI is not paying list prices, but net prices. List prices are reduced by the following regulations. Pharmacies have to pay a so-called "key account rebate" of currently 1.77 € per pack to the SHI. Patients have to pay a co-payment of 10% of the list price, but not less than 5€ and not more than 10€ per pack. The pharmaceutical industry has to pay mandatory rebates which account for 7% of the manufacturer selling price (MSP) for patent-protected drugs and 16% for generic drugs. Those mandatory rebates can be reduced by list price decreases for generic drugs or for drugs with a fixed reference price. Furthermore, manufacturers have to pay a mandatory rebate which compensates for a list price increases compared to the list price in 2009 (or to the list price at launch for newer drugs). Beside the mandatory rebates, manufacturers can make contractual agreements with SHI companies and pay "voluntary" rebates. Usually, this agreements are tenders of the SHI companies. After accounting for all those rebates and co-payments, the net price based pharmaceutical expenditure can be calculated. All measures mentioned above are regulated within the Social Security Code, Book V.

Wilcoxon sign rank tests are used to test whether pharmaceutical expenditure and other indicators differ in their annual growth rates between 2006 and 2018.

In the second part, the development of the pharmaceutical expenditure in subgroups is analysed. The overall expenditure is analysed in total as well as decomposed in changes in the volume measured by DDDs and the expenditure per DDD (i.e. cost per day). Subgroups are defined as therapeutic subgroups based on the second level of the ATC code [18]. The relevant subgroups are those belonging to the top-15 therapeutic subgroups with respect to volume or expenditure in either 2006 or 2018 according to the statistics of the Federal Health Reporting system [19]. Wilcoxon sign rank tests are used to test whether annual growth rates of DDDs, expenditure per DDD, and total net SHI expenditure differ between subgroups and the complete SHI drug market.

Data sources for the variables and structure of the drug expenditures are provided in table 1. Statistical analysis are performed with IBM SPSS, Version 25.

Table 1: Variables and data sources

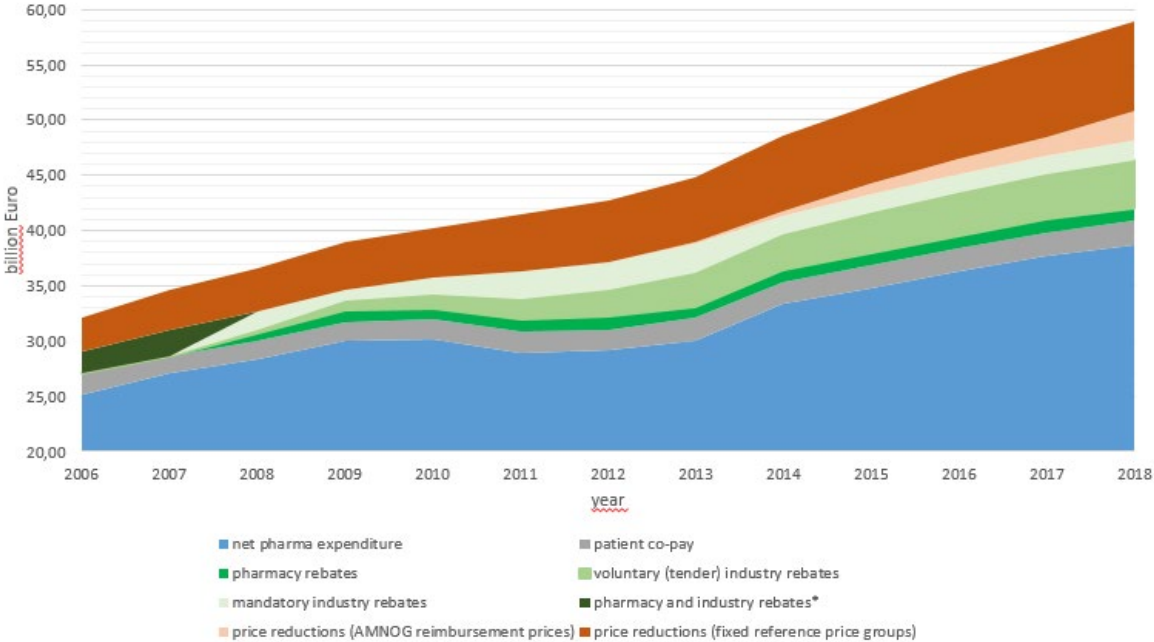
Variable	Data source
potential list price based pharma expenditure	Own calculation
- reimbursement prices (AMNOG)	[12]
- fixed reference prices	[20]
list price based pharma expenditure	Own calculation
- mandatory industry rebates	[21]
- voluntary (tender) industry rebates	[21]
- pharmacy rebates	[21]
- patient co-payments	[22,23]
net price based pharma expenditure	[24]
total health expenditure	[24]
sum of basic salaries	[25]
GDP	[26]
price index (inflation)	[27]
volume index (DDD)	[12]
price-volume-index	Own calculation
Drug expenditure by therapeutic subgroups	[28]

### 3. Results

The growth of pharmaceutical expenditures in the SHI as well as the savings from policy measures to control drug spending are illustrated in Figure 1. Between 2006 and 2018, the “potential list price” based pharmaceutical expenditure in the SHI increased from 31.1 billion € to 58.0 billion € with a compound average growth rate (CAGR) of 5.8% p.a.. In 2018, savings of 8.1 billion € could be achieved due to fixed reference prices and 2.7 billion € from list price reductions due to AMNOG benefit assessment and reimbursement price negotiations. Therefore, the “real” list price based pharmaceutical expenditure only rose from 27.1 billion € to 48.1 billion € with a CAGR of 4.9% p.a.. Due to rebates and patient co-payment, those expenditures are further reduced. Mandatory rebates of the pharmaceutical industry account for 1.7 billion € in 2018, “voluntary” rebates based on individual contracts between sickness funds and pharmaceutical industry (mainly tenders) account for 4.4 billion €, pharmacy rebates sum up to 1.2 billion €, and patient co-payments add up to 2.2 billion €. Net pharmaceutical expenditure grew from 25.1 billion € to 38.7 billion € at a CAGR of 3.7%. Between 2010 and 2013, net expenditure has been stable. One reason is that the mandatory rebate

for patent-protected drugs was set to 16% compared with 7% from 2014 onwards. This intermittent increase of the rebate aimed to achieve savings until the AMNOG reimbursement prices developed an effect. The second reason is the strongly increasing degree of implementation of tenders which started in 2008. Some policy measure provide stable savings, i.e. pharmacy rebates and patient co-payments. Savings from the pharmaceutical industry rise over time. Mandatory rebates and AMNOG reimbursement prices target mainly new, patent-protected drugs and amount to 4.3 billion € in 2018. Fixed references prices and voluntary rebates target mainly the generics industry and account for 12.5 billion € savings in 2018.

Figure 1: Pharmaceutical expenditure and savings from health policy measures in the German SHI, 2006-2018



\*: pharmacy and industry rebates have been separated until 2007 in the database

Table 2 shows the comparison of the development of the drug expenditure and indicators used to assess the sustainability of the pharmaceutical spending in the SHI. With the exemption of the price-volume-index, the potential list price based expenditure grew on a statistically significant higher rate per year than the other indicators. This illustrates the need for the increased efforts to control the expenditure growth. After accounting for list price reduction by fixed reference prices and AMNOG reimbursement prices, the list price based expenditure growth is higher than the growth of other indicators, but the difference is not statistically significant with the exemption of the volume index and the inflation. This substantiates the relevance of the measure to achieve sustainable growth. After accounting for rebates and co-payments, the growth of net expenditure no longer differs from annual growth rates of the other indicators. With a CAGR of 3.7%, net drug expenditure increased on a smaller rate than total health expenditure in the SHI (4.1%). Net drug expenditure grew somewhat faster than the sum of basic salaries (3.1%) or GDP (2.9%). Because this difference are not statistically significant, net drug expenditure does not disproportionately contribute to health care expenditure and does not imply a need to increase SHI contribution rates. Overall, the net drug expenditure does not threaten the sustainability of financing health expenditure in the SHI.



Table 2: Growth rates of expenditure and sustainability indicators

		potential list price based pharma expenditure	list price based pharma expenditure	net price based pharma expenditure
Indicator	CAGR*	p-value**	p-value**	p-value**
potential list price based pharma expenditure	5.8%	n.a	0.010	0.028
list price based pharma expenditure	4.9%	0.010	n.a	0.182
net price based pharma expenditure	3.7%	0.028	0.182	n.a
total health expenditure	4.1%	0.008	0.695	0.583
sum of basic salaries	3.1%	0.010	0.117	0.754
GDP	2.9%	0.019	0.099	0.388
price index (inflation)	1.4%	0.002	0.004	0.060
volume index (DDD)	2.8%	0.010	0.041	0.480
price-volume-index	4.3%	0.158	0.695	0.530

\*: CAGR = compound annual growth rate from 2006 to 2018, \*\*:p-value for Wilcoxon sign rank test

Drug expenditure is composed by volume and price. The data show that the growth of pharmaceutical expenditure is clearly faster than the overall inflation in the German economy (1.4% p.a.). The volume of drug consumption measured by defined daily doses (DDD) increased by 3.2% p.a. which is slightly below the growth of net expenditure. If one considers the general inflation which concern any person or company together with the increased demand for drugs, the combined growth rate (price-volume-index) is slightly above the net expenditure growth. This substantiates that the policy measures undertaken to control drug expenditure are successful in limiting net expenditure growth to a “natural” growth induced by inflation and increased demand for drugs.

In the second part, the top-15 therapeutic subgroups with respect to volume and expenditure in 2006 and 2018 are analysed (see Table 3). Twenty-five subgroups are identified. There are only limited changes in the most relevant subgroups. Some subgroups are relevant with respect to volume and expenditures like drugs used for diabetics, antithrombotic drugs, asthma and COPD drugs, lipid lowering drugs and hypertension drugs acting in the renin-angiotensin-system. Those subgroups consist of patent-protected drugs as well as generics. Some therapeutic drug groups are mainly relevant in terms of DDDs like remaining hypertension drugs, thyroid therapy and drugs for acid related disorders. The subgroups consist mainly of generics. Growth of antineoplastic drugs, immunostimulants and immunosuppressants as well as antivirals is relevant with respect to expenditure, but not to volumes. These subgroups are characterised by the highest number of new drugs during the observation period.

Table 3: Most relevant therapeutic subgroups in 2006 and 2018

ATC group	Rank DDD 2006	Rank DDD 2018	ATC group	Rank Expenditure 2006	Rank Expenditure 2018
C09 Agents acting on the renin-angiotensin system	1	1	L01 Antineoplastic agents	1	1
C07 Beta blocking agents	2	6	C09 Agents acting on the renin-angiotensin system	2	7
C10 Lipid modifying agents	3	3	A10 Drugs used in diabetes	3	3
C03 Diuretics	4	8	N02 Analgesics	4	6
A10 Drugs used in diabetes	5	5	R03 Drugs for obstructive airway diseases	5	5
C08 Calcium channel blockers	6	2	N05 Psycholeptics	6	13
H03 Thyroid therapy	7	7	A02 Drugs for acid related disorders	7	17
A02 Drugs for acid related disorders	8	2	N06 Psychoanaleptics	8	12
R03 Drugs for obstructive airway diseases	9	11	L03 Immunostimulants	9	10
G03 Sex hormones and modulators of the genital system	10	13	C07 Beta blocking agents	10	19
B01 Antithrombotic agents	11	9	L04 Immunosuppressants	11	2
C01 Cardiac therapy	12	23	J01 Antibacterials for systematic use	12	16
N06 Psychoanaleptics	13	10	C10 Lipid modifying agents	13	14
M01 Antiinflammatory and antirheumatic products	14	12	B01 Antithrombotic agents	14	4
S01 Ophthalmologicals	15	14	M01 Antiinflammatory and antirheumatic products	15	18
G04 Urologicals	20	15	L02 Endocrine therapy	16	11
			J05 Antivirals	17	8
			N03 Antiepileptics	18	15
			S01 Ophthalmologicals	23	9

Table 4 presents the growth rates in therapeutic subgroups. The growth in volume, measured by DDDs, is more pronounced than the growth in the drug prices, measured by expenditure per DDD. The overall annual growth rate of net expenditure was 3.7% and only three subgroups have shown statistically significant higher annual growth rates, i.e. antineoplastic agents, immunosuppressants and antithrombotic agents. If one looks into the growth rates of DDDs and expenditure per DDD, immunosuppressants grew stronger in both terms while oncology drugs grew significantly faster in cost per DDD and antithrombotic agents with respect to volume. These groups are characterised by a huge number of new products launched during the observation period. Compared to the three groups with an exaggerated growth in net expenditure, fourteen subgroups show growth rates which are significantly lower or even negative and counterbalance the fast growing subgroups. Generic competition and health policies targeting generic drugs, i.e. fixed reference prices and tenders, can significantly reduce drug prices, and this effect is not even counterbalanced by growth in the demand for those drugs, i.e. agents acting in the renin-angiotensin system, drugs for acid-related disorders, urologics, psychoanaleptics. Even in subgroups with many new drugs during the observation period like in diabetes, the growth is slightly below the overall development as a relevant number of patients is treated with cheaper generics like metformin or sulfonylureas. Within groups and across groups, the lifecycle of drugs and drug classes ending with generic competition – together with adequate policy measures – has a self-limiting effect on expenditure.

Table 4: Growth rates in therapeutic subgroups

Therapeutic subgroup	Expenditure (mio €)	rank	DDDs (mio.)	rank	DDD		expenditure per DDD		expenditure	
					CAGR	p-value	CAGR	p-value	CAGR	p-value
all groups					2,8%		1,0%		3,7%	
L01 Antineoplastic agents	6.089,40	1	71,50	43	-0,5%	0,182	10,7%	0,008	10,1%	0,006
L04 Immunosuppressants	6.064,40	2	161,90	30	7,1%	0,050	10,5%	0,008	18,4%	0,002
A10 Drugs used in diabetes	2.399,80	3	2.211,20	5	2,2%	0,136	2,0%	0,814	4,3%	0,875
B01 Antithrombotic agents	2.321,50	4	1.771,10	9	4,6%	0,028	5,0%	0,071	9,8%	0,034
R03 Drugs used for obstructive airway diseases	1.750,30	5	1.313,40	11	0,9%	0,004	1,7%	0,638	2,7%	0,347
N02 Analgesics	1.634,50	6	676,20	16	2,8%	0,814	-0,8%	0,117	2,0%	0,023
C09 Agents acting in the renin-angiotensin-system	1.490,30	7	9.161,10	1	5,5%	0,002	-6,6%	0,003	-1,5%	0,023
J05 Antivirals for systemic use	1.324,80	8	46,80	46	4,9%	0,071	3,5%	0,754	8,6%	0,583
S01 Ophthalmologicals	1.162,50	9	791,50	14	1,5%	0,182	7,6%	0,008	9,3%	0,117
L03 Immunostimulants	1.017,00	10	20,10	53	-1,9%	0,004	2,7%	0,308	0,8%	0,117
L02 Endocrine therapy	918,70	11	153,00	32	1,8%	0,156	3,4%	0,084	5,3%	0,158
N06 Psychoanaleptics	885,80	12	1.702,30	10	5,3%	0,006	-6,0%	0,002	-1,0%	0,006
N05 Psycholeptics	777,20	13	538,90	18	-0,5%	0,002	-2,2%	0,308	-2,7%	0,023
C10 Lipidmodifying agents	708,80	14	2.436,90	3	2,0%	0,034	-2,8%	0,050	-0,9%	0,034
N03 Antiepileptics	687,80	15	435,10	20	5,1%	0,002	-2,2%	0,239	2,9%	0,754
J01 Antibacterials for systemic use	651,80	16	310,30	27	-0,4%	0,041	-1,2%	0,136	-1,7%	0,028
A02 Drugs used for acid related disorders	628,60	17	3.639,70	2	8,9%	0,010	-12,1%	0,002	-4,3%	0,004
M01 Antiinflammatory and antirheumatic products	598,20	18	1.040,60	12	1,2%	0,015	-0,8%	0,099	0,4%	0,034
C07 Beta blocking agents	568,30	19	2.132,20	6	0,6%	0,003	-3,9%	0,012	-3,3%	0,003
C03 Diuretics	415,40	22	1.803,40	8	0,0%	0,003	0,2%	0,48	0,2%	0,01
H03 Thyroid therapy	372,70	24	1.805,70	7	2,6%	0,937	-0,2%	0,338	2,4%	0,308
G03 Sexhormones and modulators of the genital system	330,70	29	818,70	13	-2,8%	0,002	0,8%	1	-2,0%	0,002
G04 Urologics	329,20	30	690,60	15	5,9%	0,002	-5,7%	0,005	-0,2%	0,041
C08 Calcium channel blockers	251,50	33	2.238,90	4	3,3%	0,814	-6,9%	0,003	-3,9%	0,002
C01 cardiac therapy	248,70	34	350,40	23	-7,7%	0,002	6,0%	0,006	-2,1%	0,008
others	6.250,40		5.064,10		2,1%	0,182	0,8%	0,814	2,9%	0,209

p-value according to Wilcoxon signed rank test, CAGR = compound annual growth rate from 2006 to 2018

#### 4. Discussion

Based on ethics and health economics, one needs to balance the need to make drugs financially accessible to patients who need them – this refers to coverage and reimbursement decisions as well as to financial sustainability – and to keep pharmaceutical companies viable and profitable [29]. The presented study shows that within the German SHI financial sustainability of net pharmaceutical expenditure is achieved and a wide variety of different regulating mechanisms have been established for this purpose. The policies support the natural effect of the life-cycle such that generic competition across and within therapeutic groups absorbs growth in groups with many new, innovative drugs. The mechanisms established in Germany favour generic drugs with respect to physician prescribing and automatic substitution in pharmacies, but the generic industry suffers disproportionately from price regulations. While patent-free drugs account for 57% of sales, health policies targeting mainly on generic drugs are threefold compared with policies targeting at patent-protected drugs. Price regulation appears to be imbalanced between patent-protected and off-patent drugs. Therefore, one should carefully monitor future developments across the groups and focus additional efforts on regulation of new drugs.

Balderrama et. al supposed a model of “enlightened risk sharing” to balance patients, insurance and industry needs [29]. Today, risk sharing is widely unavailable in Germany and focussed on very high-priced drugs like CAR-T-cell therapies [30]. Furthermore, the relevance of risk-sharing agreements on the sustainability of financing has been questioned [31] and some countries use this agreements mainly for discounts or free doses [32].

AMNOG reimbursement prices are based on a benefit assessment, but not on cost-benefit assessment and all drugs are reimbursed, i.e. the SHI cannot exclude drugs from reimbursement if price negotiations are going to fail. Germany is among the very last countries to establish health economic criteria for reimbursement decisions or price finding decisions [33]. It would be a major disruption in the German SHI system, if drugs would be excluded based on cost-benefit analysis. Non-reimbursement as in the UK, France and other countries appears not to be suitable in Germany. It has recently been argued that cost-effectiveness based pricing could not prevent sky-rocketing of drug prices and it was supposed to consider thresholds for minimum improvement in order to substantiate higher prices [34]. A stronger focus in clinical and economic considerations including such thresholds could be considered as an option for further development of the AMNOG process.

Espin et al. analysed pharmaceutical expenditure in five European countries and explicitly considered net prices, i.e. list prices minus rebates and clawbacks. Their results suggest that future growth in pharmaceutical expenditure in Europe is likely to be lower than previously understood from forecasts based on list prices, below predicted healthcare expenditure growth in Europe and in line with long-term economic growth rates. For policy makers concerned about the sustainability of pharmaceutical expenditure, their study may provide some comfort, in that the perceived problem is not as large as expected [35]. The study on the German situation presented here is in line with their results.

## 5. Conclusions

It is important for policymakers to understand pharmaceutical spending trends and factors that influence them in order to formulate effective cost containment strategies and design optimum drug policy in order to achieve financial sustainability [4]. The study analysed the development of SHI drug expenditure between 2006 and 2018 in Germany based on official statistics.

Net pharmaceutical expenditure in the German SHI increases by 3.7% p.a. The growth is limited by several policy measures to control drug expenditure. While measures targeting pharmacies (rebates) and patients (co-payments) are stable, the contribution of the pharmaceutical industry to the savings by list price reductions, i.e. fixed reference prices and AMNOG reimbursement prices, and net price reduction, i.e. mandatory and voluntary rebates, is rising. Policies targeting the generics industry lead to threefold higher savings than those targeting originator companies which shows an imbalance of the measures.

As a result of the policy measures, annual net drug expenditure growth rates do not significantly differ from the total SHI health expenditure, the relevant income of the SHI members and the gross domestic product. The net drug expenditure growth correlates with the combined effects of overall inflation and the increased demand for drugs. As pharmaceutical companies face overall inflation this explains a part of the growth. The other factor is an increased demand which can be induced by changes in demography and epidemiology, but also as consequence of drugs use which prolongs life and thus results in longer treatment of chronic diseases. Conclusively, net expenditure growth is sustainable and adequate.

Only few subgroups with a high number of new drugs launched at high prices grow faster than average. This exaggerated growth is counterbalanced by smaller growth or even decline in a huge number of therapeutic subgroups mainly due to generic competition. The lifecycle of therapeutic classes and policy measures like fixed reference prices and tenders which mainly target generic drugs mutually boost each other and, until today, achieve enough financial scope for sustainable funding of new, innovative drugs. As a conclusion, the growth of net drug expenditure does not threaten the sustainability of financing health care in the German SHI. However, growth across therapeutic subgroups shall be monitored to identify the need for further policies to control expenditure growth originating from fast growing subgroups and new drug launches.

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