Health economics letter

n° 99 - October 2005

questions d'économie de la santé

Issues in health economics analysis

Background

This study forms part of the IRDES programme of research on pharmaceutical policy, and compares the regulatory framework and contents of baskets of reimbursed drugs in three European countries: France, Germany and England. It is a contribution to the current debate on reimbursement of drugs of insufficient therapeutic value, which the High Authority on Health has recently proposed will no longer be reimbursed.

Comparisons of baskets of reimbursed drugs are made on the basis of lists of reimbursed specialties (the positive list) for France, and on lists of medicines not reimbursed by the state (negative lists) for Germany and England. We base our account of the regulatory frameworks in each country on a literature review supplemented by institutional contacts.

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ISSN : 1283-4769

Diffusion by subscription: 60 € per annum

Price of the number: 6 €

On line on sur www.irdes.fr

10 to 15 numbers per annum

The politics of drug reimbursement in England, France and Germany

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Pharmaceutical expenditure, which has doubled during the last ten years, is a major concern in France, as in most other industrialised countries. However, France stands out for its level of expenditure: twice as high as in England and one and half times higher than in Germany. All these countries use specific lists defining the drugs that are reimbursed by public funds (positive list) or not taken in charge (negative list) to control their drug expenditures. Do these lists have any impact on the extent of reimbursement? And does the content of the drug baskets explain the differences in consumption between these countries?

Three categories of drugs for which these countries have adopted different strategies are studied: benzodiazepines, vasodilators and life style drugs (obesity, tobacco addiction etc.). It seems that the size of the drug basket reimbursed is independent of the positive or negative nature of the list. Moreover, these examples reveal that it is not the number of products available in the basket that explains the variations of drug expenditure between the countries, but the differences in doctors' prescription behaviour. The experiences of our neighbours suggest that it is important to put in place tools for controlling drug demand including in particular, financial incentives for more rational prescription and consumption. This is shown by England's experience, which, in contrast to the other countries, reimburses anti obesity and smoking cessation drugs yet manages to control its overall drug expenditure.

General information and drug reimbursement in the study countries, 2003

	France	Germany	England
Pharmaceutical market [1]			
Pharmaceutical expenditure [2] (% public expenditure on health)	18,4	13,9	12,3
Public expenditure per capita in $ PPP [2]	326	238	208
Private expenditure per capita in $ PPP [2]	198	110	50
Pharmaceutical production per capita in $ PPP [3]	573	302	343
Exports per capita in $ PPP	317	278	332
Regulation			
Type of list used	positive	negative	negative
Prescribing budgets	-	For doctors (target volume)	For general practices (fixed budgets)
Price control	Negociations + reference price (TFR)	Reference price *Festbetrag*	Profit control (PPRS)

Source : Eco-Santé OECD 2005, report of the House of Commons 2005

1) All data per person are given in US dollars converted on the basis of purchasing power parity (PPP). PPSs are rates which enable the conversion of prices to a common currency by eliminating purchasing power differences between currencies.

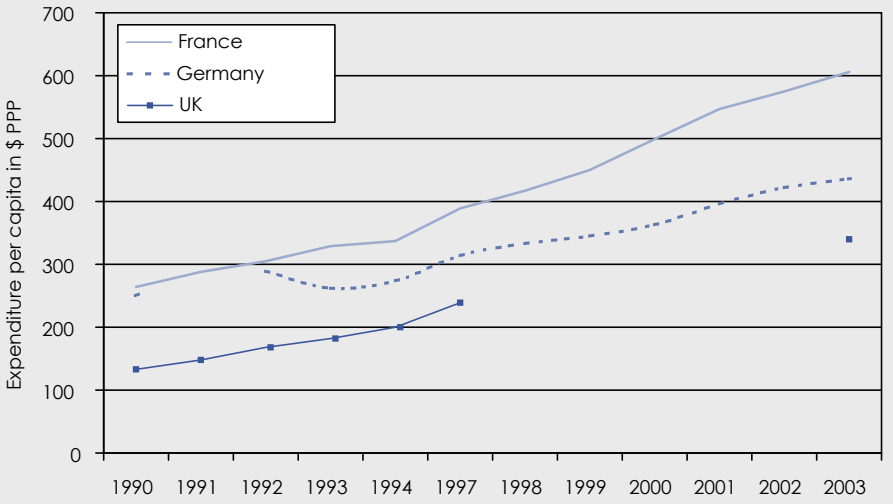
2) Expenditure on drugs consumed in ambulatory sector.
3) Corresponds to the United Kingdom.

With an expenditure of 30 billion Euros in 2004, France is known for its high levels of pharmaceutical consumption. Public expenditure on drugs is among the highest in OECD countries, accounting for more than 18% of public expenditure on health, and is increasing more rapidly than in most other countries (see table p.1 and the figure opposite).

Coinciding with a new evaluation of pharmaceutical products by the High Authority on Health, this study compares the approach taken to define the form and content of the basket of reimbursed drugs in two neighbouring countries. We have selected England[1] and Germany for this comparison, two countries with relatively big pharmaceutical industries, very active in regulation, and which have been more successful in controlling their pharmaceutical consumption than France. In fact, although pharmaceutical expenditure was comparable in France and Germany in the early Eighties, the rate of increase has declined significantly in Germany during the last ten years (see figure below). In contrast England has always had a lower level of consumption, and has monitored the levels of public expenditure on pharmaceutical consumption carefully, and continues to develop new policies to regulate supply as well as demand.

France uses an explicit list to define products reimbursable by the sickness insurance scheme, whereas England and Germany use negative lists which specifies those products which are not reimbursed. The idea behind these lists is to concentrate public expenditure on «useful products» i.e. on products which contribute to the treatment of illness deemed «serious», which are effective in treating these illnesses, and for those cases the least costly. Nevertheless, the criteria used to define the form of the basket of reimbursable drugs and the methods for evaluating products do differ significantly between these countries. How do these criteria influence the final content of the reimbursed basket? And beyond this, to what extent do differences in the content of these baskets explain the differences in consumption between these countries?

Growth in total per capita pharmaceutical expenditure in Germany, France and the UK



Sources: Eco-Santé OECD 2005; IRDES estimation for the UK 2003 (based on a report for the House of Commons 2005)

We begin by reviewing the decision rules governing drug reimbursement as well as the related methods used to control supply and demand in the three countries. Then we compare reimbursed drug baskets for three areas where the countries have adopted different strategies: products at risk of abuse, in particular the benzodiazepines; medicines where there are doubts about efficacy, in particular vasodilators; and drugs designed to improve quality of life such as treatments for erectile dysfunction, for obesity and for tobacco addiction.

Regulation of drug reimbursement

Germany: recent restrictions in reimbursed drugs

In Germany, any new drug entering the market must undergo a clinical evaluation. Authorisation for market entry, which is valid for five years and renewable, specifies how it will be made available: by prescription or not, restricted to sale in pharmacies or not.

Pharmaceutical companies are free to set prices. Nevertheless a high proportion of the market (60% in volume) is governed by reference prices (*Festbetrag*).These reference prices which were introduced in 1989, set a reimbursement ceiling for groups of comparable medicines.

Principles for compiling lists

Any pharmaceutical product on the market is reimbursed by the sickness insurance funds (GKV) insofar as it does not belong to one of the categories defined by law. The reform of 2004 redefined the basket of drugs reimbursed by these funds, excluding many products. Hence drugs for which a prescription is not required are no longer reimbursed, even if they are prescribed, except where they are used in the standard treatment of serious conditions, or for children under twelve.

For persons aged over eighteen, certain drugs for which a prescription

[1] *We describe the rules which apply in England and Wales. These can differ somewhat from those in Scotland and N. Ireland.*

is required, are not reimbursed, particularly those for treating flu and colds (including analgesics and cough mixtures), laxatives etc.. The law also states that the Minister of Health, in agreement with the Minister of the Economy and Parliament, can on his own initiative exclude drugs which are usually prescribed for minor health problems.

Similarly, drugs where the main indication is for improvement in quality of life, are not reimbursed. The 2004 law also ended the debate, at least provisionally, concerning those drugs (such as treatments for obesity and erectile dysfunction) which had been excluded from reimbursement as soon as they entered the market.

Finally, it confirmed the exclusion of 'non-economic' drugs defined as follows: drugs which contain ingredients which are not indispensable for the therapeutic objective, drugs whose action is not clear due to the presence of numerous active ingredients and drugs for which the therapeutic benefit has not been proven. Hence, the label 'non-economic' refers to a drug's efficacy rather than any economic evaluation.

The Joint Federal Committee (GBA), which groups doctors' federations, sickness insurance funds and hospitals, plays a key role in defining the basket of drugs to be reimbursed. It specifies the conditions where drugs which do not require a compulsory prescription are reimbursed and compiles the negative lists.

Other regulatory measures

The regulations which define the basket of reimbursable drugs are accompanied by other measures designed to control drug prescribing. Since 1998, a system of target volumes of prescription for each doctor, adjusted by specialty and data for the previous year, has been in place. If the volume of prescriptions exceeds this target by more than 15%, this must be justified by the doctor. If the target is exceeded by more than 25%, repayment may be required. These target volumes, which have replaced regional budgets, are the main means of regulating drug prescription.

The GBA is also responsible for developing recommendations for good clinical practice. These recommendations are enforceable by law and doctors may be penalised for bad practice.

There is a system of copayments, for which the method of calculation and levels of payment have varied during the last ten years. Until 2003, this consisted of a payment related to the size of the drug package. Since 2004, this has been 10% of the sale price, with a minimum of 5 € and a maximum of 10 €. This copayment is paid in full by the patient, but there are many exemptions. (In 2001, almost half of all prescriptions were exempt). For drugs with a reference price, the difference between the sale price and the reference price is added to the copayment.

France: slow implementation of the new principles for determining reimbursement lists

In France, in order to be commercialised a drug must obtain an Authorisation for Market Entry (Autorisation de mise sur le marché, AME) from the French Agency for the Health Safety of Health Products (*Agence française de sécurité sanitaire des produits de santé, AFSSAPS*). Depending on the product's characteristics, the new drug may be available without prescription, or only under prescription.

Moreover in France the prices of reimbursed drugs are directly controlled. The prices are negotiated between the pharmaceutical company and the Economic Committee for Health Products (*Comité économique des produits de santé, CEPS*) and must take into account the drug's improvement in therapeutic value (*Amélioration de service médicale rendue, ASMR*)[2], the price of comparable drugs on the list and the anticipated volume of sales. Since September 2003, a system of reference prices, called the responsible payment tariff (Tarif forfaitaire de responsabilité, TFR) was introduced for groups of generics with an insufficient level of market penetration. Historically drug prices have been lower in France than in the other big European markets, in particular the German and British markets. Today, the price of new products is close to the European average.

Principles for establishing the positive list

In order to be reimbursed, a drug must be included in the list of pharmaceutical specialties reimbursable under social insurance (the positive list)[3]. Inclusion in this list is decided by the Ministry of Health and Social Insurance, with advice from the Transparency Commission. This Commission, under the supervision of the High Authority on Heath (*Haute Autorité de la Santé, HAS*) since August 2004, evaluates the therapeutic value *Service Médical Rendu* (SMR) and the improvement in therapeutic value *Amélioration du Service Médical Rendu* (ASMR) of the drug. If the SMR is deemed sufficient, the Commission recommends its inclusion in the list and establishes the level of reimbursement: 35%, 65% or 100% depending on the SMR (weak, moderate or high) and the severity of the condition to be treated. Inclusion in the list may be limited to certain indications. Between the end of 1999 and 2001, the Transparency Commission has evaluated the therapeutic value of 4490 reimbursa-

[2] *The ASMR compares the therapeutic value of a drug with other treatments available for the illness.*

[3] *This concerns medicines prescribed in general practice. Drugs dispensed in hospitals and other organisations must appear in the list of specialties agreed for organisations.*

[4] *The Transparency Commission is now part of the Hignh Authority on Health.*

ble specialties. It recommended that 835 should be removed from the list because their SMR was inadequate. Since then, only 72 have been removed. Because the Transparency Commission's evaluations have been vigorously contested by the pharmaceutical companies, the High Authority on Health[4] is ask to carry out a new evaluation of theese drugs (763) in 2004. The results for drugs for which prescription is not obligatory were made public in September 2005. Among the 403 specialties examined, 364 were again judged to be of inadequate therapeutic value. They will no longer be reimbursed from March 2006, with the exception of veinotoniques which will be reimbursed at 15% until 2008. A second round of evaluation has been announced for prescription drugs.

Comparison of reimbursed drug baskets, 2002

	France	Germany	England
Number of molecules reimbursed			
Benzodiazepines	20	18	10
Vasodilators	15	14	9
Erectile dysfunction	1	0	9
Anti-obesity	0	0	5
Smoking cessation	0	0	2
Public expenditure euros/1000 inhabitants			
Benzodiazepines	2615	1185	1108
Vasodilators	3829	1440	181
Erectile dysfunction	50	0	1027
Anti-obesity	0	0	1108
Smoking cessation	0	0	906

Sources: Medic'AM 2002; PACT 2002; *Arzneiverordnungs report 2003*

Other regulatory measures

In 1994, regulatory practice guidelines (*Références médicales opposables, RMO*) were introduced with a view to identifying treatments and prescription drugs which were of no therapeutic value, or dangerous. They had a real impact on doctors' behaviour as soon as they were established. Their impact has declined since then, particularly since abolition of the sanctions envisaged at the outset. Since 2002, there have been agreements between doctors and the sickness insurance fund in specific areas in an attempt to improve the quality of care (AcBus).

A copayment, called the 'ticket modérateur', remains the responsibility of the insured. It is set in proportion to the price of the product and may be 35% or 65% depending on the drug. It should be noted that more than 90% of the population has supplementary insurance which usually covers the whole copayment.

England: between rationing by budgets and medico-economic analysis

Entry to the market in England requires the authorisation of the Medicine and Healthcare Product Regulatory Agency (MHRA). Drugs are classified as medicines available only under prescription (Prescription only Medicine), available only in pharmacies (Pharmacy only) or available for general distribution (General Sale List). Hence, pharmacies do not have a monopoly of drug sales.

Drug pricing is not controlled, but the profits made by pharmaceutical companies are regulated by the Pharmaceutical Pricing Regulation Scheme (PPRS), an agreement between the pharmaceutical industry and the Department of Health. The PPRS fixes a threshold for profits (currently 21%). If this is exceeded (more than 40%), the company must return the excess to the NHS or lower its prices the following year.

Principles of list development

At the national level (NHS), decisions about drug reimbursement are taken by the Department of Health. The concerned parties are consulted: the pharmaceutical industry, doctors' representatives, pharmacists, patients and the National Institute for Clinical Evaluation (NICE). The Department establishes two lists:

- A negative list which specifies those drugs which doctors can not prescribe within the NHS (a black list);
- A restrictive list which determines the molecules whose prescription is reimbursed for certain indications and categories of individuals (a grey list).

Six groups of products cannot be prescribed: 1) products excluded on medico-economic grounds – for a list of 17 categories of medicines, only the least expensive versions are reimbursed (analgesics, laxatives, benzodiazepines, etc.); 2) substances which are not medicines; 3) products available for sale out of pharmacies for which the manufacturer sets a price too high for the NHS; 4) drugs which may be misused; 5) products whose cost cannot be justified within the priorities of the NHS; 6) products administered by pre-filled injection if a cheaper alternative exists.

The cost and the cost-effectiveness ratio are therefore key criteria in determining whether to reimburse. Furthermore NICE, an independent institute, assesses the economic and clinical effectiveness of all drugs submitted to it for evaluation.

Any medicine on the market is by default reimbursed by the NHS provided that it is not on the negative or restrictive lists.

Since January 2002, the NHS is legally obliged to finance drugs and treatments recommended by NICE.

Other regulatory measures

Outwith the measures described above, doctors' prescribing practice is largely governed by locally determined rules. Local organisations of groups of health professionals (doctors and nurses) known as Primary Care Trusts (PCTs) are responsible for the financial management and organisation of ambulatory health care. Doctors are responsible for their prescribing budgets and each PCT establishes a list of drugs which they will reimburse, and stipulates good prescribing practice. Since 2002, a favourable recommendation from NICE means that a treatment must be made available locally. In effect these are used as positive lists by doctors in PCTs.

Patients contribute to the cost of drugs by paying a charge for each prescribed medicine. In 2004, this copayment was £6.40 (approximately €10) for each item. However there are many exemptions and 85% of NHS prescriptions are exempt from co-payments.

This relatively high charge would appear to encourage self-medication which accounts for about 30% of pharmaceutical expenditure in the UK, compared to approximately 15% in France and Germany.

In all three countries medico-economic evaluation has become increasingly important in the regulation of drug reimbursement. Nevertheless, the relative importance of these evaluations and the criteria used do vary between the three, with England pursuing this approach most vigorously. Our neighbours are also taking numerous initiatives to control demand by monitoring prescribing and increasing copayments.

Comparison of reimbursement policy for three classes of drugs

Following this description of the general regulatory framework for reimbursement, we compared France, England and Germany in three areas where the countries have taken different approaches: drugs where there is clear misuse and hence a public health problem, medicines whose efficacy is disputed, and treatments designed to improve quality of life.

Products with an established risk from misuse: reimbursement of benzodiazepines

The benzodiazepines are an old class of molecules, used in the treatment of insomnia, anxiety and epilepsy. However these drugs are physically and psychologically addictive and hence susceptible to misuse and abuse. The supply of these products is regulated in each country for reasons of public health and security. In England benzodiazepines are classed as narcotics, and their possession and distribution are restricted. In France as in Germany, the period for which they may be prescribed is limited (to between four and twelve weeks), but there is little control of repeat prescribing.

A detailed comparison of the molecules which are reimbursed in the three countries shows that of 20 products reimbursed in France (17 at 65%), half of these are neither reimbursed nor on the market in England. The others are only reimbursed in their generic form. The German basket is almost identical to that of France and almost all of the drugs are subject to reference pricing, compared to France where only one is. The reimbursement rates in France comply with the recommendations of the Transparency Commission, which has given these products an SMR of important or moderate.

Reimbursement of benzodiazepines in 2002 cost (per 1000 inhabitants): more than €2600 in France, more than €1200 in Germany and €1100 in England. With a similar basket, France spends twice as much as Germany.

Products of questionable efficacy: the example of vasodilators

Drugs in this class are indicated for diseases of the arteries or arterioles, cerebrovascular disease, visual problems of vascular origin and certain cognitive deficits in older persons. However, their efficacy has been questioned for most of these indications. In France in 2001, the Transparency Commission judged them of insufficient therapeutic value. This decision was contested, and the vasodilators are due to be reevaluated soon. Hence they are still on the reimbursed list. In Germany, the vasodilators are not on the negative list, but they have been classed by the sickness insurance schemes as medicines of uncertain efficacy.

Data source

Positive and negative lists

England: Schedule 1 and 2 published in March 2004 in Drug Tariff (03,04)

Germany: Negativlist published November 16, 2000 (still in force at the time of writing), texts of the SGB-V and Arzneimittel Richtlinien (AMR).

Molecules and products were identified on the basis of Vidal© (www.rote.list.de) in Germany and the British National Formulary in England.

France: SEMPEX/VIDAL©, 27/04/2004 edition.

Supplementary data for calculating costs and on reimbursed molecules:

Prescribing Analysis and Cost© 2002 (PACT© in England: Arzneiverordnungs-report 2003 and publications of the GBA (AMR, Festbeträge) in Germany, Medic'Am 2002 in France.

Among the 37 molecules registered in this class, 16 are reimbursed in France (all at 35%), 15 in Germany (all at reference prices) and 9 in England. In 2002, the total reimbursed by the sickness fund for these products in France amounted to approximately €228 million (€3829 per 1000 inhabitants), despite a considerable reduction in the number of packages sold during the last 5 years. Although the basket of reimbursed drugs is identical in Germany, the public cost of these drugs is considerably lower (€1440 per 1000 inhabitants). In England, vasodilators accounted for only £6 million (€181 per 1000 inhabitants) in 2002.

These differences in consumption are principally due to differences in prescribing behaviour among doctors. One study carried out by the French Mutuals using prescription data from IMS-Health shows that French doctors prescribe on average 17 lines of vasodilators per 100 inhabitants, compared to 11 in Germany and 1 in England[5].

Drugs designed to improve quality of life

The distinction between improving quality of life and reducing health risks is not clear and is often debated. Here we look at three examples: treatments for erectile dysfunction, obesity and tobacco addiction.

In France and in Germany, these products are not generally reimbursed[6] (except alprostadil in France[7] for treatment of erectile dysfunction in certain situations).

Surprisingly, England reimburses 9 molecules for erectile dysfunction, two for smoking cessation and 5 for weight loss. Although the reimbursement of drugs indicated for the treatment of erectile dysfunction is clearly delineated by the restrictive list, access to the other products does not differ from that for other drugs. Nevertheless, NICE recommends the reimbursement of these products[8] in precise circumstances (diet having already started for example) and on condition that their prescription is accompanied by other therapeutic measures (such as attendance at a smoking cessation clinic).

It is important to note that in England obesity is a priority area for action in public health. This is explained by the relative prevalence of the condition: obesity affects 22% of the population in England, 10% in France and 13% in Germany. With the same concern to protect public health, the NHS also supports assistance in smoking cessation. Finally, the NHS has decided to reimburse 9 molecules for the treatment of erectile dysfunction, for precisely defined medical situations. We may surmise that this decision reflects the belief that specific measures to control prescribing will prevent abusive use of these products.

In 2002, the NHS spent almost €55 million for anti-obesity drugs, €45 million for smoking cessation products and €50 million for treatments for erectile dysfunction.

* * *

This comparison of reimbursed drugs in the three countries studied suggests that the type of list used (negative or positive) does not have any significant effect on the amplitude of the baskets of reimbursed medicines. An expectation that the development of a positive list, a time-consuming exercise, could lead to a more restricted reimbursed basket, is not borne out by the examples we have selected. However it is difficult to carry out a more global analysis of the positive list used in France, because the criteria specified for its compilation are not always applied.

The three examples presented here also show that the size of the basket reimbursed does not explain differences in consumption. Although the basket of products reimbursed for benzodiazepines and vasodilators is comparable, France consumes twice as much as Germany.

The examples of medication for obesity and smoking cessation show that the reimbursement decisions are also related to national values and priorities. Hence the strong focus on public health in England leads the NHS to reimburse these drugs.

Finally, the data on the prescription of vasodilators indicate some fundamental differences in prescribing behaviour. It seems that the use of budgets or individual prescribing volumes, as well as direct financial incentives, have had an effect on the prescribing habits of English and German doctors.

[5] *Prescription and consumption of drugs of insufficient therapeutic value (SMRI): an international comparison. Study Summary, March 2005, Mutualité Française.*

[6] *Provision free of charge of nicotine substitutes to disadvantaged persons attending health centres is being tested in France as part of the Cancer Plan.*

[7] *In Germany, alfrostadil is only reimbursed for the indication of arteriopathy of the lower limbs.*

[8] *Bupropion for smoking cessation, orlistat and sibutramine for weight loss, alprostadil and phentolamine for erectile dysfunction.*

Further information

Nguyen-Kim L., Or Z., Paris V., Sermet C. *Pharmaceutical reimbursement ploicy in Germany, England and France*, IRDES Report, to be published, October 2005.

See as well:

Busse R., Schreyogg J., Henke K. 2005. *Regulation of Pharmaceutical Marketsin Germany: Improving Efficiency and Controlling Expenditures?* Int J Health Plann Manage 20: 329-349.

Walley T., Mrazek M., Mossialos E. 2005. *Regulating Pharmaceutical Markets: Improving Efficiency and Controlling Costs in the UK.* Int J Health Plann Manage 20: 375-398.