

# Lif's views on reimbursement...



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## **Lif's views on reimbursement...**

### **Reimbursement should support and promote the best possible healthcare for patients**

#### **Reimbursement is granted to patients**

Reimbursement is granted to patients, not pharmaceuticals. It is important to remember this. It is equally important to acknowledge that reimbursement is a significant factor in the use of pharmaceuticals and the quality of healthcare. Public reimbursement is therefore a core healthcare and distribution policy instrument.

Whereas treatment with medicinal products at public hospitals is free for patients in Denmark, this is generally not the case when treatment with pharmaceuticals is provided outside hospitals in the primary health sector. In fact, most healthcare services are free for patients, also outside the hospitals, but patients have to make a financial contribution when the health service offerings include use of pharmaceuticals.

#### **Reimbursement influences behaviour**

In principle, and slightly theoretically, reimbursement which subsidizes "private" goods is regarded as a positive counterpart to user payment in which payment is required for a public service. But for patients needing treatment, in reality these are two sides of the same matter. The historical background for not making pharmaceuticals free for patients is that it is thought that this would cause greater usage than could be justified on the basis of proper healthcare provision. The design of the reimbursement system is thus fundamentally to influence behaviour and on this basis, it is surprising how little is fundamentally known in the healthcare system about the consequences of the reimbursement rules on behaviour and distribution.

## **The reimbursement system**

The public reimbursement system means that when patients purchase medicinal products, a public subsidy is granted for the provision of certain pharmaceuticals. The level of reimbursement depends on the individual's usage of pharmaceuticals entitled to reimbursement and this only occurs when usage exceeds a certain level (DKK 465 in 2007).

Reimbursement is not available for all the pharmaceuticals given to patients. Reimbursement (general reimbursement) is not automatically available for approximately 40% of new pharmaceuticals. It is the Danish Medicines Agency that decides whether reimbursement should be granted for a medicinal product. The Agency has the option of restricting reimbursement to groups of patients for whom the Agency finds it especially appropriate, for some reason or other, to grant reimbursement ("general conditional reimbursement"). The Danish Medicines Agency uses this option very rarely. Instead, the Agency extensively bases the reimbursement system on individual reimbursement ("single reimbursement") which requires the attending physician to apply to the Danish Medicines Agency on behalf of the patient for reimbursement for that individual patient.

The Danish Medicines Agency is advised in its decisions on reimbursement by the Medicines Reimbursement Committee which consists of up to seven members. As a general rule, members have backgrounds as medical professionals. The Reimbursement Committee makes recommendations in cases dealing with the reimbursement status of pharmaceuticals and a limited volume of individual applications for reimbursement.

**Single reimbursement – in theory a safety net, but misused in practice**

Many of the rejections issued by the Danish Medicines Agency for general and general conditional reimbursement are based on the “risk assessments” made by the Agency; this includes whether the Agency finds that there is a risk of products being used by patients with other diseases than those for which the Agency feels reimbursement should be granted. The Agency’s decisions are often based on simple price comparisons.

The option of awarding single reimbursement is a classic “safety net”, that is a scheme intended to ensure reimbursement is awarded in very special instances in which the patient can benefit from a pharmaceutical without general or general conditional reimbursement having been granted. However, the practice of the Danish Medicines Agency has not followed this original philosophy since in reality it uses two different types of single reimbursement, namely:

1. Decisions on “purely single reimbursement”, i.e. decisions made in accordance with the original basic philosophy underlying the single reimbursement scheme.
2. “Conditional single reimbursement”, i.e. groups of patients that have been pre-defined by the Danish Medicines Agency as entitled to reimbursement.

Whereas purely single reimbursement is to a certain extent approved with the involvement of the Reimbursement Committee, the process of dealing with the cases of conditional single reimbursement is extensively automated since special guidelines and “check box” forms have been drawn up for some pharmaceuticals. Even though conditional single reimbursement is not an official category, the practice of the Danish Medicines Agency is such that this form of reimbursement has replaced general conditional reimbursement to a very considerable extent.

**The single reimbursement scheme creates geographical differences in the use of medicines**

Considering that in addition to the automation of the scheme and that two thirds of applications for single reimbursement are submitted by hospital doctors and consulting specialists, it is not clear what medical contribution is provided by the Danish Medicine Agency’s “second opinion” in these cases. Expert contributions appear, however, to be very limited and thus the Danish Medicine Agency’s practice appears to reflect a lack of confidence in doctors being willing to administer general conditional reimbursement in accordance with the rules.

GP's receive no payment from the National Health Service for submitting an application for single reimbursement unlike other types of application such as applications for chronic or terminal reimbursement. The doctor may therefore charge the patient. This "extra payment" undoubtedly constitutes a not inconsiderable additional cost for certain patients.

In several ways this inappropriate administration of the single reimbursement scheme constitutes a barrier for access by patients to new pharmaceutical treatments. The scheme therefore contributes to creating differences between doctors, and hence also geographic differences in the use of pharmaceuticals. It also means that the introduction and spread of new treatment options is slower than in other countries.

The Danish Medicines Agency is required to regularly reassess previous decisions on reimbursement so as to assess whether the preconditions on which the original decision to grant reimbursement was based still apply. Reassessments of individual pharmaceuticals are expected to be undertaken every fifth year. The reassessment of the first group of pharmaceuticals was concluded in the spring of 2007.

**Danish VAT distorts the competition between Denmark and the other EU countries**

Danish patients cannot currently receive reimbursement for pharmaceuticals bought in other countries; a fact that has attracted criticism from various parties. For certain pharmaceuticals, there are from a consumer's point of view considerable differences in prices in EU member states.

Consumer prices may vary for many different reasons, including differences in cost structures, distribution systems, reimbursement rules and countries' tariff/duty systems. For example, Denmark has the EU record for value added tax (VAT). This means that patients pay 25% VAT on pharmaceuticals in Denmark whereas there is no VAT on prescription pharmaceuticals in Sweden. Market conditions thus differ considerably between countries.

**Counterfeit medicines are cheap, but hazardous to health**

Buying and selling medicinal products is covered by a whole range of special regulations intended to cut risks and enhance patient safety. Buying pharmaceuticals in other countries is especially challenging with respect to the high level demands for safety in distribution and the requisite consumer information.

The trade in counterfeit pharmaceuticals is a growing international problem. Patients who unintentionally buy counterfeit pharmaceuticals are often exposed to a health risk. Counterfeiting is expected to constitute a special problem when buying pharmaceuticals in other countries via the Internet.

**Lif's view is,**

- Reimbursement is granted to patients and not pharmaceuticals and that reimbursement is important for the quality of healthcare treatment. Public reimbursement is therefore a core healthcare and distribution policy instrument, and accordingly political awareness should be directed at how the rules are formulated and administered in practice when handling cases for reimbursement.
- The reimbursement system should support the best possible healthcare for patients, including the optimal use of pharmaceuticals in the Danish health service.
- Making general reimbursement conditional for specific illnesses is an appropriate way of supporting the optimal use of pharmaceuticals in cases where the regulatory authorities find no basis for granting reimbursement to everyone using a given medicinal product.
- When submitting applications for reimbursement, it should be possible for companies to apply for general reimbursement as well as general conditional reimbursement.
- The Danish Medicines Agency should trust the willingness and ability of doctors to administer pharmaceuticals covered by general conditional reimbursement in accordance with the rules. Treatment guidelines, lists of recommendations and prescription monitoring by the regulatory authorities are effective instruments for countering inappropriate application of the scheme.

- The single reimbursement scheme should only be used as a safety net for very special cases. Used as originally intended to cover exceptions, the single reimbursement scheme can be a useful tool.
- The regulatory authorities are responsible for ensuring that the single reimbursement scheme does not make barriers for patients and doctors. This means at the very least that patients should receive sufficient information about the scheme and that its use should not predicate patient payment. For doctors, the Danish Medicines Agency should ensure good information and easy administrative procedures.
- In all decisions on general reimbursement, the Danish Medicines Agency should consult the relevant scientific bodies and patient associations.
- The Reimbursement Committee that advises the Danish Medicines Agency in matters of reimbursement should be expanded to include representatives with special economical skills given the considerable importance given to financial considerations in reimbursement cases.
- Decisions on reimbursement should be made on the basis of objective and controllable criteria. The decision-making processes of the regulatory authorities and their procedures should be transparent and it should be possible for both companies and patients to have recourse to another appeal body in testing all parts of the Danish Medicine Agency's decisions.
- It is fundamentally sensible to regularly reassess previous decisions provided that this is based on the consequences for treatment of patients. Reassessments should at the very least conform to the same requirements for principles, methods and procedures as those involved in the initial decisions on reimbursement. Rescinding reimbursement should depend on the availability of new scientific documentation.
- Public reimbursement for Danish patients should continue to be restricted to the purchase of pharmaceuticals in Denmark for reasons of safety and the markets' structures.

## **The socio-economic value of pharmaceuticals should always be considered**

### **Improved treatment options take many forms**

In cases of general reimbursement for pharmaceuticals, the Danish Medicines Agency must give weight to the prices of pharmaceuticals being commensurate with their therapeutic value, meaning that there should be a financial as well as a therapeutic assessment.

The introduction of novel pharmaceuticals often means that patients receive new, improved treatment options. Improvements may be apparent in several ways: greater efficacy, fewer side effects, greater ease of use/administration, etc. For some pharmaceuticals, progress is very considerable, others less so per se but they may constitute a necessary step in an ongoing development in a therapeutic area.

### **Narrow considerations and "silo mentality" counteract optimum choices**

Enhanced therapeutic efficacy and hence less illness must generally be assumed to have a range of economic benefits, for example by way of fewer admissions to hospital or visits to doctors and society should also be able to benefit by way of quicker return to work and daily life. An analysis of costs and benefits of new pharmaceuticals can thus not meaningfully be automatically restricted to the immediate, direct costs and benefits of the medicinal product and neither should it be limited by sector limits (silos) selected more or less by chance. In contrast, all factors such as costs and benefits within and outside the health service should be considered, also including the consequences of such disparate elements as differences in patient compliance, differences in usage of services in the primary healthcare sector, the hospital sector and the social sector and the impact on the family and other social relations. The point is that the limits should be set on the basis of relevance.

These many multifaceted factors may be identified in so-called health- or socio-economic studies. It should be self-evident that the regulatory authorities, who make decisions on behalf of us all, should in some way or other identify all such relevant factors.

**The authorities use simple price comparisons**

We currently have a scheme in which the pharmaceutical companies can voluntarily submit a socio-economic analysis when applying for reimbursement. The fact that the scheme is voluntary and aimed at the companies does not exempt the regulatory authorities from making qualitative assessments of the same factors when making decisions on reimbursement on the basis of economical considerations. Nowadays the practice of the Danish Medicines Agency is that decisions are often based on a simple comparison of prices for the novel pharmaceutical compared to the previous forms of treatment combined with a more or less implicit supposition that there are no significant differences in therapeutic outcome.

**Need for systematic assessments of advantages and disadvantages**

It is no secret that it has always been difficult to make precise statements of the magnitude of net gains associated with novel pharmaceuticals, or of other new forms of treatment for that matter. This is due to the uncertainty attaching to all studies, medical or financial. But a systematic assessment of the advantages or disadvantages would in any event provide a better foundation for making a decision than unsystematic and sporadic information. Accordingly, decision-makers have, when applying a systematic basis irrespective of the uncertainty, a better chance of making decisions within the framework of the reimbursement regulations as well as assessing how public reimbursement for medicinal products should be applied in supporting rational and optimal use of pharmaceuticals.

**Lif's view is,**

- When considering new medicines, decisions on reimbursement should take into consideration all socio-economic aspects of the use of the pharmaceutical. Economical assessments should broadly include relevant gains and costs inside and outside the health service.
- Better, more widespread use should be made of health economics methods and studies than is currently the case when assessing the rational use of pharmaceuticals in the Danish health service.
- Assessment of the significance of a pharmaceutical for treatment of disease or prevention of disease should be based on the same principles applied in a medical technology assessment, namely the technology itself, its significance for patients, the organisational framework and Economical considerations.

- Assessments of pharmaceuticals should be made on the same terms and according to the same principles as those used to assess other healthcare technologies. This should also mean that the same organisational unit is used to assess the societal impact of the introduction of all new technologies in the Danish health service.



Lægemedel  
industri  
foreningen

Strødamvej 50A  
DK-2100 København Ø  
info@lif.dk

Tlf: 39 27 60 60  
Fax: 39 27 60 70

[www.lif.dk](http://www.lif.dk)